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Diabetes Screening in Inmates: A Quality Improvement Pilot Project

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Diabetes Screening in Inmates: A Quality Improvement Pilot Project

Mary Ellen Castro, DNP

University of Connecticut, 2014

Abstract

Implementation and adherence to screening recommendations of Type 2 Diabetes (T2D) clinical practice guidelines are associated with earlier diagnosis and treatment. Standardized T2D screening helps ensure consistency of care and decrease unnecessary testing by targeting those at greatest risk for developing the disease. The aim of this quality improvement pilot project was to facilitate standardized T2D screening of inmates within a correctional system. The number and frequency of selected preexisting major T2D risk factors identified within a sample of inmates diagnosed during incarceration were described. A clinical panel reviewed these data and identified the guideline that best addressed T2D risk in the sample. Implementation of guideline screening recommendations as a prospective quality improvement study in a broader sample was proposed prior to considering statewide application.

Keywords: diabetes, screening, inmates, prisoners, corrections

Diabetes Screening in Inmates: A Quality Improvement Pilot Project

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B.S.N., Western Connecticut State University, 1988

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A Dissertation

Submitted in Partial Fulfillment of the

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University of Connecticut

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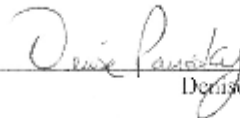
Doctor of Nursing Practice

Diabetes Screening in Inmates: A Quality Improvement Pilot Project

Presented by

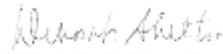
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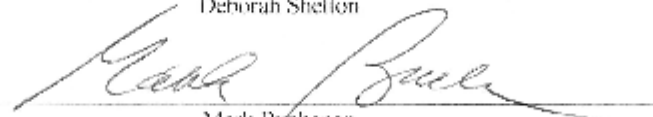
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DEDICATION



I dedicate this effort to the One who loves, forgives, awakens, enlightens, guides, teaches, nourishes, shapes, protects, strengthens, and saves us.

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Chapter One

Type 2 diabetes (T2D) is a major national health problem accounting for 90 to 95% of all diagnosed diabetes cases in adults (CDC, 2011). With an aging population and increasing rates of obesity and sedentary lifestyles, the national incidence of T2D is increasing (Koller, Chin, and Conway, 2013). Diabetes prevalence in correctional settings is predicted to increase as the population of inmates serving long sentences ages and new inmates who are at risk for T2D are incarcerated (ADA, 2011a, 2013a). Due to poor health habits and limited access to health care prior to incarceration, inmates having T2D might be unaware they have the disease when they enter the correctional system (Dumont et al., 2012). Others could have risk factors for T2D and develop the disease during incarceration. Inmates with unrecognized T2D are not afforded early treatment or education interventions that might control diabetes progression and potentially avert complications (Weber, Twombly, Narayan, and Phillips, 2011).

Type 2 diabetes has a gradual progression and it is estimated that 10% to 23% of those with impaired fasting glucose (prediabetes) develop T2D within five years of diagnosis (Rich et al., 2013.) Type 2 diabetes screening helps identify those who are at increased risk for developing the disease and may benefit from diagnostic testing and health education interventions aimed at normalizing glucose regulation (ADA, 2011a, 2013a; Perreault et al., 2012). Those not identified at risk for T2D might not receive these interventions (Chamnan et al., 2012; Murphy and Winmill, 2013).

Diabetes imposes an increasingly significant healthcare burden. Estimated total United States diabetes expenditures increased 41 %, from \$174 billion in 2007 to \$245 billion in 2012, and are predicted to rise in tandem with increased prevalence projections (ADA, 2013c). Although diabetes expenditure data has not been reported by correctional systems, as care is

constitutionally commensurate with that of the community, the impact of diabetes on correctional budgets is believed to be major (ADA, 2009; Kinsella, 2004). Delayed diagnosis and treatment of T2D in inmates can result in costly comorbid conditions which burden not only correctional systems, but the community, as the majority of inmates are eventually released (Chettiar et al., 2012; Williams et al., 2012). Type 2 diabetes screening in inmates may reduce these expenditures (Lee et al., 2010; Tomlinson and Schechter, 2002).

Implementation and adherence to T2D screening recommendations of correctional diabetes clinical practice guidelines (CPGs) are associated with earlier diagnosis and treatment (ADA, 2013b). Adherence to guidelines promotes a culture of patient safety and is a recommended performance measure to assess correctional health care services (Greifinger, 2012; Stern, Greifinger, and Mellow, 2010). Although T2D screening in inmates is recommended by the National Commission on Correctional Health Care (NCCHC), Federal Bureau of Prisons (FBOP), and the American Diabetes Association (ADA), not all inmates who might benefit may be screened (Binswanger, Krueger, and Steiner, 2009; Tomlinson and Schechter, 2002). As correctional diabetes screening recommendations vary, unless one guideline is selected to standardize care within a correctional system, prescribers might be uncertain as to which of several guidelines to follow (CDC, 2010; Spencer, 1999). Others may question the method by which the diabetes CPGs from which screening recommendations were derived had been developed (Casagrande, Cowle, and Fradkin, 2013; Lawler, 2009; Muhlhauser and Meyer, 2013).

Screening for diabetes and other chronic diseases can help identify those who might benefit from diagnostic testing, quantify those at risk for disease, and anticipate future health care service needs (ADA, 2011a, 2013a; Mears and Cochran, 2012). Although direct screening

costs are estimated to be at least partially offset by a simultaneous reduction in future diabetic complication expenses, unrecovered expenditures associated with negative tests results can be difficult to support (Tomlinson and Schechter, 2002). Implementation and adherence to screening guidelines that target screening to those who might benefit most can reduce costs associated with over- or under screening (Chatterjee, et al., 2013; Dans et al., 2011; Rich et al., 2013). In addition, the selection of one T2D screening guideline for state wide implementation could improve consistency of care, decrease targeting errors, and reduce the risk of missing those who might benefit from screening.

Purpose

The purpose of this quality improvement pilot project was to facilitate standardized T2D screening of inmates within a correctional system, specifically, to describe the number and frequency of selected major T2D risk factors in a sample of inmates diagnosed with T2D during incarceration, for review by a clinical panel tasked with identifying the guideline screening recommendations that best addressed T2D risk in the sample.

Problem

Delayed diagnosis and treatment of T2D can result in costly comorbid conditions which burden not only correctional systems, but the community, as the majority of inmates are eventually released (Chettiar et al., 2012; Williams et al., 2012). Targeted screening can identify those at increased risk for developing diabetes and who might benefit from diagnostic testing, interventions aimed at preventing diabetes, and early treatment to prevent disease progression if diabetes is subsequently found (ADA, 2011a, 2013a; Perreault et al., 2012; Weber, et al., 2011). Diabetes screening in inmates is recommended by correctional diabetes

management guidelines, but not all inmates who might benefit are screened (Binswanger, Krueger, and Steiner, 2009; Tomlinson and Schechter, 2002).

In the absence of being guided to utilize one correctional screening guideline within a system, practice among correctional health providers may be inconsistent. Variations can result in delayed or over-testing, both of which can generate unnecessary costs. Differences in screening approaches can also make it more difficult to complete disease prevalence and therapeutic control comparisons necessary for evaluation and reporting purposes (Borysova et al., 2012). In addition, variations in T2D screening practice could potentially invite malpractice litigation.

The selection of a T2D screening guideline should consider the population to which it is intended to apply. In an effort to limit screening to those who might benefit most and realize potential cost savings, screening those at greatest risk for developing T2D is advocated (Chatterjee et al., 2013). However, care must be taken to not exclude a substantial number of those who might also benefit from screening (Casagrande et al., 2013; Sheehy et al., 2010). Without a description of the number and frequency of retrievable T2D high risk factors within an inmate population, the guideline selected for implementation may be inappropriate.

Theoretical Framework

The theoretical framework selected for this pilot project is rooted in the preventive maintenance philosophy of Leavell and Clark (1953). Although this framework is not as current as other frameworks, it is still relevant because its health promotion precepts specifically address the focus of this project - diabetes screening.

From an epidemiological perspective, Leavell and Clark (1953) expanded upon existing preventive medical knowledge to increase disease prevention and health promotion awareness.

Disease was perceived as a dynamic process that follows a natural progression and involves environmental interaction. Leavell and Clark (1953) defined preventive medicine as “the science and art of preventing disease, prolonging life, and promoting physical and mental health and efficiency” (p. 7). Effective preventive medicine was viewed as halting disease progression as early as possible, studying causes and effects, recognizing contributory environmental factors, and implementing interventions to impede or stop the advancement of disease or disability.

Within the framework of preventive medicine, five primary levels of prevention were identified: health promotion, specific protection, early recognition and prompt treatment, disability limitation, and rehabilitation (Leavell and Clark, 1953). Health promotion concerned efforts directed to promote overall wellness and included promotion of appropriate nutrition and adequate exercise. Specific protection was deemed the primary focus of preventions intended for individuals and focused on preventing disease. Early disease recognition and prompt treatment were meant to prevent or cure a condition when possible, halt disease progression and prevent complications, and limit the duration of impairment. Disability limitation referred to the delay of complications associated with advanced disease states. Rehabilitation consisted of physical, mental, and social aspects of care that would prevent total disability and enable the person to contribute usefully to society.

Leavell and Clark (1953) considered screening a health promotion activity as it heightened awareness of modifiable factors associated with the onset of a specified disease. An underlying premise to screening was that disease followed a natural progression during which signs warranting further evaluation might be identified. This evaluation would either exclude the presence of the disease state or lead to diagnosis. Early diagnosis and management of disease was deemed essential to preventing its progression and any disabling comorbidity.

Screening as a Health Promotion Activity. Leavell and Clark (1953) noted that patients who had been diagnosed with diabetes and received appropriate treatment in the early stages of disease had better outcomes than those diagnosed at later stages of disease progression. Successful therapeutic interventions included the promotion of nutrition and other health hygiene activities through patient education. The prevention and timely management of diabetes-related complications were believed to decrease disability and lessen socioeconomic burden. Based on their observations, Leavell and Clark (1953) asserted that diabetes was one condition for which screening could and should be done. Their early preventive medicine precepts are congruent with current Healthy People 2020 goals and objectives.

Healthy People 2020 goals include the attainment of high quality and longer lives through the prevention of disease, disability, injury and death for all population groups (U.S. Department of Health and Human Services, 2010). Prevention initiatives which reduce the incidence and socioeconomic burden of diabetes and improving quality of life of those with or at risk for the disease are advocated. Primary prevention objectives address increasing the proportions of people at risk for diabetes who report increased physical activity, attempted weight loss, and reduction in dietary fat or calories. Secondary prevention objectives include increasing the proportions of adults screened for diabetes and then enrolling found to have diabetes enrolled in formal diabetes education programs. Tertiary prevention objectives stress increasing the proportion of diabetics achieving normal glucose control and decreasing the proportion of those with diabetes-related complications.

Assumptions

1. Targeted T2D screening identifies inmates who might have the disease and may benefit from subsequent diagnostic testing and future inmate health education programs.

2. The selection of screening recommendations of one guideline for systemic use can reduce the risk for inappropriate or unnecessary, duplicative, or missed T2D screening in those who might benefit.

3. Standardized T2D screening may decrease expenditures associated with unnecessary screening or conditions associated with delayed diagnosis.

Pilot Project Questions

1. What is the number and frequency of selected preexisting major T2D risk factors in a sample of adult male inmates diagnosed with diabetes during incarceration within one state correctional system?

2. Which correctional diabetes guideline screening recommendations best addresses T2D risk in the sample?

Definition of Terms

Type 2 diabetes (T2D).

Theoretical: “A metabolic disorder characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both” (WHO, 2003, p. 1), specifically, measured glycosylated hemoglobin (HgbA1c) of 6.5% or more or serum Fasting Blood Glucose (FBG) of 126 mg/dl or more (ADA, 2013a; ADA, 2013b).

Operational: Type 2 diabetes diagnosis documented in the inmate health record by the correctional physician, nurse practitioner, or physician assistant.

Major type 2 diabetes (T2D) risk factors.

Theoretical: A condition or attribute strongly associated with the development of T2D.

Operational: Age ≥ 45 ; BMI ≥ 25 ; systolic blood pressure (SBP) ≥ 140 or diastolic blood pressure (DBP) ≥ 90 or currently prescribed antihypertensive therapy; three or more consecutive treated or untreated SBP measurements of ≥ 135 or DBP ≥ 80 ; fasting high density lipoprotein level (HDL) ≤ 35 or fasting serum triglyceride level ≥ 250 mg or currently prescribed lipid lowering therapy; history of impaired fasting glucose/prediabetes (HgbA1c of 5.7 to 6.4 or FBG of 110 to 125 mg/dl); being of black, Hispanic/Latino, Native North American, or Asian descent; or coronary vascular disease.

Inmates with type 2 (T2D).

Theoretical: Inmates diagnosed with T2D.

Operational: Inmates who are currently prescribed oral medications to treat T2D and have a documented diagnosis of T2D in the inmate health record.

Screening.

Theoretical: The process whereby asymptomatic individuals who have not sought care for a specific health problem for whom detection might benefit are found to have the problem (WHO, 2003).

Operational: The act of testing non-diabetic inmates who are asymptomatic for T2D to determine if there is a possibility that they might have the disease.

Summary

The prevalence of T2D in correctional settings is predicted to increase as the population of inmates serving long sentences ages and new inmates who are at risk for T2D are incarcerated. Those not identified at risk for T2D might not receive interventions aimed to prevent or decrease morbidity and mortality. Screening can identify those at risk for T2D as well as those who might benefit from diagnostic testing. Guidelines help target screening to those

who might benefit most while decreasing unnecessary expenditures. As the prevalence of T2D risk factors can vary between populations, it was appropriate to identify the number and frequency of selected major T2D risk factors within a sample of adult male inmates within the correctional system to ascertain if screening could be targeted to specific risk factors. A clinical panel reviewed these data and identified the guideline that best addressed T2D risk in the sample. Implementation of guideline screening recommendations as a prospective quality improvement study in a broader sample was advised prior to considering statewide application.

Chapter Two

Diabetes screening and management guidelines are associated with improved clinical outcomes (Giorda et al., 2012). Adherence to guidelines promotes a culture of patient safety and is a recommended performance measure to assess correctional health care services (Greifinger, 2012; Stern et al., 2010). Implementation and adherence to guidelines target screening to those who might benefit most and reduce costs associated with unnecessary screening (Dans et al., 2011; Rich et al., 2013).

A comprehensive search of the 2003-2013 literature conducted using PubMed, CINAHL, Medline, and Google Scholar databases for “diabetes AND screening AND inmates (OR prisons OR jails OR corrections” found no empirical research reported on this topic. Consequently, this review of the literature examined research pertaining to theoretical and empirical support of T2D screening and empirical evidence reporting the prevalence of T2D and selected major risk factors within the correctional population.

Type 2 Diabetes Screening

Justifications for T2D screening include the increasing prevalence of the disorder, the recognized asymptomatic nature of incipient diabetes, the substantial number of individuals with T2D who are undiagnosed and unaware of a need for intervention, and a long preclinical period in which detection can occur (World Health Organization [WHO], 2003). During this time, interventions aimed at preventing or delaying the onset of T2D can be initiated. WHO (2003) reports that early diabetes detection and treatment can increase the length and/or quality of life, reduce costs associated with diabetes complications, and help reallocate these expenditures to competing priorities. These precepts are congruent with Leavell and Clark’s (1953) Preventive

Medicine framework and Healthy People 2020 objectives (U. S. Department of Health and Human Services, 2010).

Justifications for T2D screening are supported by findings of the Diabetes Prevention Program (DPP) (The Diabetes Prevention Program Research Group [DPPRG], 2002) and the Diabetes Prevention Program Outcomes Study (DPPOS) (Perreault, et al., 2012). The DPP study was conducted to determine if lifestyle intervention (diet and exercise) or metformin therapy might decrease T2D risk in a sample (n=3,234) of pre-diabetic obese individuals (DPPRG, 2002). Participants from 27 clinical sites across the United States were followed for an average of 2.8 years (DPPRG, 2002, p. 393). Sixty-eight percent of the subjects were female and the mean age of the sample was 51. Forty-five percent of the sample belonged to a racial or ethnic minority group (20% African American, 16% Hispanic, 5% American Indian, 4% Asian or Pacific Islander). At the conclusion of the study, it was reported that those who adhered to the lifestyle intervention regimen had decreased T2D risk by 58 percent; those who adhered to the Metformin regimen decreased T2D risk by 31 percent (DPPRG, 2002, p. 393).

Eligible study DPP participants (n=2,846) were subsequently enrolled in the ten year follow-up DPPOS (Perreault et al. (2012). Among those who had continued lifestyle intervention, T2D incidence was decreased by 43 percent; among those who continued Metformin therapy, T2D incidence was decreased by 18 percent (Perreault, et al., 2012). As the DPP and DPPOS were conducted in the United States and included a significant sampling of racial ethnic minority populations, these findings may be useful to support ongoing T2D screening and interventions to decrease T2D risk in correctional settings having similar racial ethnic inmate characteristics.

In addition to the DPP and DPPOS findings, WHO T2D screening precepts were also supported by a regression analysis which associated improved cardiovascular outcomes and lower all-cause mortality with the implementation and adherence of a diabetes screening and management guideline within an Italian national healthcare setting (Giorda et al., 2012). In contrast to these findings, those of other European studies differed.

The Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (ADDITION) was the first large multi-national randomized intervention study investigating the response to intensive intervention to reduce morbidity and mortality in those diagnosed with T2D following screening (Griffin et al., 2011). Screening was targeted using age, gender, BMI, hypertension, and steroid use criteria. Subjects had previous access to national health care services health care. Fifty-eight percent of the subjects were male and the mean age of the sample was approximately 60 years (Sandback et.al., 2008, p. 30). Subjects who were not Caucasian (white) comprised 5 percent of the sample (Sandback et.al., 2008, p. 30).

Comparing the effect of early intensive interventions against usual care in the management of screen detected T2D, researchers for the ADDITION-Europe (n=3057) and ADDITION- Denmark (n=1533) arms of the study reported that those who received intensive intervention had a small and non-significant reduction in cardiovascular events over 5 and 6 years respectively (Charles, et al., 2013; Griffin et al., 2011). Findings for the ADDITION-Cambridge (n=20,184) arm suggested that compared with usual management of screen detected T2D, intensive intervention did not significantly reduce cardiovascular or all-cause mortality over 10 years (Simmons et al., 2012). As both those in the intensive and normal care groups in

all arms of the study received appropriate care, it would be premature to abandon T2D screening recommendations based solely on these findings.

In addition, as it was not possible to have included a no-treatment group, the benefits of intensive or usual care against no care, could not be quantified. It was also not known if findings would have varied in a different predominant racial/ethnic group. Therefore, ADDITION study results should be interpreted cautiously by United States correctional systems having inmate population characteristics different from ADDITION samples.

Under the premise that the characteristics, progression, and potential complications associated with diabetes meet criteria for which screening is appropriate, T2D screening of individuals at risk is recommended (ADA, 2011a, 2013a; WHO, 2003). National correctional professional practice standards recommend diabetes screening in inmates to improve diabetes outcomes and help prevent comorbidity (ADA, 2008b, 2013b; FBOP, 2010; 2012; NCCHC, 2009, 2013).

In the resource-sensitive correctional environment wherein pressing safety and security concerns may supersede healthcare ideals, prioritization of efforts to manage acute and known health problems is not uncommon. Although costs related to T2D screening are estimated to be at least partially offset by simultaneous reductions in expenses related to the treatment of diabetes related complications, unrecovered costs related to negative tests results can be difficult to justify (Tomlinson and Shechter, 2004). Initiating evidence based measures to help decrease the number of costly negative test results is warranted. There is some support to begin universal T2D screening in the community starting between ages 30 and 45 (Kahn, et al., 2010). Although universal screening is believed to be more cost-effective than not screening, greater benefit is believed to be attained through a targeted approach (Chatterjee, Narayan, Lipscomb, and

Phillips, 2010). Investigating cost-effectiveness of T2D screening in hypertensive and general populations, Hoerger et al. (2004) found that targeted screening would be more cost-effective than universal screening and that screening of individuals between 55 and 75 of age would be most efficacious. Other research suggests that screening would benefit those 45 and older who are at above average risk for T2D (Gillies et al., 2008).

The review of the literature found no findings that clinical research has been conducted to study the benefits of T2D screening in inmates. WHO and ADA advocate T2D screening in all at risk populations under the premise that reductions in long-term complications and socioeconomic costs would be achieved (CDC, 2010). The U.S. Preventive Services Task Force (USPSTF) analyzed data from previous studies to investigate if screening and early detection and treatment of T2D improved healthcare outcomes (2008). Based on its review, USPSTF found that although aggressive treatment of hypertension in diabetics reduced cardiovascular complications by 50%, there was no evidence to support that earlier T2D detection improved the outcomes of those with diabetic visual impairments or renal compromise.

National Prevalence of Diabetes and Major Diabetes Risk Factors in Inmates

Due to variations in correctional system data collection and tracking methods used to report disease incidence in United States correctional settings, accurate national prevalence data may be lacking. When only 19 of 41 states responded to a NCCHC survey for its 2004 report, *The Health Status of Soon-to-Be Released Inmates*, reported that they collected prevalence data on diabetes, hypertension, heart disease, or asthma, prevalence data needed to be estimated from the community population (Lincoln, et. al., 2010, p. 513). Although the capabilities of well-designed electronic health records (EHRs) can facilitate the collection, tracking, and reporting of disease prevalence data based on documented diagnoses, the majority of state correctional

systems have not yet implemented them (Bisset and Harrison, 2012; Woodward, 2010). Consequently, the United States national prevalence of diabetes and major diabetes risk factors in inmates has been based on self-report surveys and prevalence projection studies. Comparative community prevalence estimates provide useful reference information, and these data were included in the review of studies that reported these data. As the literature estimating the prevalence of major diabetes risk factors was predominantly found in studies estimating diabetes prevalence, study design and strengths and weaknesses were the same for all content within these studies.

Diabetes. To help understand the impact of chronic diseases on correctional and community health systems, Hornung, Greifinger, and Gadre (2002) used a projection model to estimate the prevalence of medical conditions including diabetes. These researchers selected data from the third National Health and Nutrition Examination Survey (NHANES-III), which had been obtained from laboratory findings and based on established diagnostic criteria, as the community population reference standard to estimate disease prevalence. Specific age-adjusted gender and race/ethnicity rates for the U. S. population age 17 and older was derived from 1990 U.S. Census data and applied to 1995 National Institute of Justice (NIJ) jail and prison inmate population estimates (Hornung, Greifinger, and Gadre, 2002, p. 40). Application of NHANES-III data to inmate population estimates was done to estimate disease prevalence in inmates.

A second analysis was undertaken to estimate disease prevalence in the subgroup of inmates who belonged to the low socioeconomic (SES) group believed to be most representative of the inmate population (p. 40). Calculations for both analyses were based on weighted 1995 national criminal justice prison population statistics (which may not have been representative of the state correctional system where this pilot project was conducted). Diabetes prevalence

estimates were made based on the fasting serum glucose ≥ 140 mg/dL diabetes diagnostic criterion accepted when NHANES-III was conducted (1988 to 1994) as well as that revised standard which was adopted in 1997 and lowered fasting serum glucose to ≥ 126 mg/dL.

Based on the > 140 mg/dL or greater fasting serum glucose diagnostic criterion, it was estimated that 4.9% of community, 3.0% of federal prison inmates, 2.0% of state prison inmates, and 1.8% of local jail inmate populations had diabetes. Adjusted diabetes diagnostic criterion to fasting serum glucose 126 mg/dL or greater increased prevalence estimates to 7.6, 5.2, 3.3, and 3.0% respectively. Diabetes prevalence was generally estimated to be higher in the low SES subgroups. In each analysis, diabetes prevalence was estimated to be higher in the community than the correctional setting. Diabetes estimate differences between inmate populations were attributed to variation in age demographics.

A major strength of the study undertaken by Hornung et al. (2002) was the use of a diabetic community reference standard that had been based on objective findings and established diagnostic criteria. Through this and the application of essential demographic data, more accurate estimates of diabetes prevalence were made. However, the precision of estimate projections was compromised by the inability to account for behavioral and education preparation factors linked to health habits and that possibly differ between community and correctional populations.

A different approach to estimate the prevalence of chronic diseases was undertaken by the U.S. Department of Justice's Bureau of Justice Statistics (BJS). Specifically, the collection and analysis of jail and prison inmate survey data in the 2002 Survey of Inmates in Local Jails (SILJ) which was published in the 2006 Medical Problems of Jail Inmates report and the 2004 Survey of Inmates in State and Federal Correctional Facilities (SISFCF) (BJS, 2007; James, 2004; Maruschak, 2006). According to health information obtained as part of SILJ, 2.7% of jail

inmate respondents (n=5872) self-reported diabetes (James, 2004; Maruschak, 2006). Prevalence increased with age, ranging from 0.6% of inmates in the 24 or younger age group to 8.4% of those 45 or older. Estimates were higher among respondents to SISFCF. In this survey, 4% of state (n=12,846) and 5.1% of federal (n=3,119) prison inmates self-reported diabetes. Similar to SILJ findings, diabetes prevalence increased with age, with prevalence in state prisons ranging from 0.4 % in inmates age 24 or younger to 11.3 % in those 45 and older, and prevalence in federal prison ranging from 0.7 % to 12.9 %. Comparing overall prevalence estimates between SILJ and SISFCF, diabetes prevalence was lowest in local jail (2.7%) and highest in federal prison (5.1%) inmate populations. The observation that these prevalence estimates, which were based on self-report data are lowest among inmates incarcerated in local jails and highest in those remanded to federal prisons, is consistent with that made by Hornung et al. (2002) using their projection model.

Primary strengths of both SILJ and SISFCF surveys included large national sampling, relevant and comprehensive data collection, and a superior response rate that exceeded 84%. A significant limitation to the SILJ and SISFCF was the inability to validate inmate responses to questions about disease states through confirmatory diagnostic testing. Another major limitation was the potential for measurement errors due to under- or over-reporting of health conditions. Reasons for doing so include unfamiliarity with terms used to describe a health condition, misapprehension regarding the purpose or use of the survey, mistrust of those who obtain or review responses, literacy or processing deficits, and language barriers. Inmates might also be unaware of having a medical condition as screening or diagnosis prior or during incarceration might not have been done.

Wilper et al. (2009) analyzed SILJ and SISFCF sample data in order to formulate prevalence estimates for chronic diseases. Sample weights supplied by BJS were applied to account for nonresponse and survey design and yield national correctional estimates (Wilper, et al., 2009, p. 668). Age-adjusted comparisons were then made with 2003-2004 National Health and Nutrition Examination Survey III (NHANES-III) community estimates. Following analysis of the inmate sample inclusive of non-respondents, it was estimated that 11.1% of those (n=3,686) in federal prisons, 10.1% of those (n=14,499) in state prisons, and 8.1% of those (n=6982) in local jails had diabetes. By applying age-standardization to 2000 U.S. census data,, not only were the correctional population prevalence estimates appreciably higher than those reported in earlier studies, but they also exceeded the 6.5% community diabetes prevalence estimate based on NHANES-III data (Wiper et al., 2009, p. 688). The latter finding differs from the Hornung et al. (2002) estimate of greater diabetes prevalence in the community population.

Similar to previous research, among correctional populations diabetes prevalence was estimated to be lowest in jail inmates and highest in federal prison inmates. According to a comparison of SILJ and SISFCF demographic data by Wilper et al. (2009), the percentage of inmates 50 or more years of age was 11.1 in federal prisons, 8.6 in state prisons, and 4.2 in local jails. As the prevalence of T2D increases with age, these data helped explain prevalence differences between correctional settings.

The predominant strength of the investigation undertaken by Wilper et al. (2009) was the incorporation of age-adjusted comparisons that more precisely estimated chronic disease estimates in inmates. As prevalence estimates were greatly dependent on SILJ and SISFCF inmate self-reporting data, the lack of confirmatory testing to validate responses would apply to this study as well.

Binswanger et al. (2009) estimated the prevalence of diabetes and other chronic medical conditions by age group and between correctional settings and the community. Sample data from SILJ and SISFCF were analyzed to estimate prevalence in jail (n=6582) and prison (n=14,373) populations. National Health Interview Survey-Sample Audit Files (NHIS-SAF) data from 2002, 2003, and 2004 were used as the reference sample for the community population (n=76,597). After pooling data and weighing survey sources to ensure that non-responses had been accounted for and estimates were representative of the target populations, logistic regression was used to compare prevalence between populations. Prevalence was estimated by age group—18 to 33, 34 to 49, and 50 to 65 – and predicted to increase with age. Estimated diabetes prevalence in jail inmates ranged from 1.5% in the 18 to 33-year-old age group to 14.4% in the 50 to 65-year-old age group. Respectively, prevalence range in prison inmates ranged between 1.6 and 15.2%. Community diabetes prevalence estimates for identical age groups ranged between 1.1 and 11.4%. Following adjustment for race, education, place of birth, marital status, and alcohol consumption, diabetes prevalence estimates between correctional and community populations were found to be comparable (Binswanger et al., 2009, p. 914). This finding is incongruent with those reported by Hornung et al. (2002) who estimated that diabetes was more prevalent in the community population and Wilper et al. (2009) who estimated that diabetes was more prevalent in the correctional population.

The principal strength of the research by Binswanger et al. (2009) included the comprehensive analysis of SILJ and SISFCF demographic, behavioral, and socioeconomic survey data. Consequently, more exact disease prevalence estimates were achieved. As was noted in the study by Wilper et al. (2009), limitations of the SILJ and SISFCF surveys would also apply to this research.

Aging. As in the community, older inmates are more likely to develop T2D as well as chronic conditions known to increase diabetes risk. The correctional population is aging as many are serving long sentences prompted by stricter sentencing legislation enacted in the 1980s and 1990s. According to the 2009 Bureau of Justice Statistics (BJS) report, 20.0% of the total sentenced state and federal prisoner population (n=1,613,740) was 45 years of age or more (West, Sabol, and Greenman, 2010). Based on existing federal demographic data and sentencing trends, it is estimated that estimate that 30% of inmates will be 50 years of age or older by 2030 (Chettiar et al., 2012). These data were collected using reliable standardized methods.

Overweight and Obesity. Overweight and obese individuals, classified as having a body mass index (BMI) of 25 or more, are at increased risk for T2D (ADA, 2011). Although there is abundant literature noting the increasing prevalence of obesity in the community, research estimating the prevalence of diabetes among correctional populations is scant. As part of their research investigating the prevalence of chronic conditions, Binswanger et al. (2009) estimated the prevalence of overweight and obesity. Binswanger et al. (2009) estimated that prevalence of overweight (BMI 25 to 29.9) and obesity (BMI \geq 30) was lowest in the 18 to 33 age group and highest in the 50 to 65 age group in each population (jail inmate, prison inmate, and community). Overweight was estimated to be lower in the community (28.8% to 38.4%) and higher in the prisons (40.7% to 49.8%). Conversely, obesity was predicted to be generally higher in the community (18.4% to 29.1%) and lower among jail inmates (13.9% to 22.1%).

Hypertension. Hypertension is directly associated with the development of T2D (ADA, 2011). According to findings from the chronic disease prevalence research undertaken by Hornung et al. (2002), hypertension prevalence was higher in the community population (24.5%) than the overall correctional population (16.7%). At 28.6% and 18.3% respectively, this finding

was also found among low SES groups. Between correctional groups, prevalence was lowest among local jail inmates (14.7%) and highest among federal prison inmates within the low SES group (21.6%).

Findings from the SILJ and SISFCF were used to estimate hypertension prevalence within and between inmate populations. Based on SILJ data, 11.2% of all local jail inmates reported hypertension. Prevalence increased with age and ranged from 5.3% in the 24 or younger age group to 26.1% in the 45 or older age group (Maruschak, 2006). Overall prevalence among state and federal prison inmates responding to the SILJ survey was higher at 13.8 and 13.2% respectively (BJS, 2007). As was found among jail inmates, prevalence increased with age. This ranged from 3.4% in state prison inmates age 24 or younger to 30.6% in those 45 and older and 2.1% and 28.4% in federal prison inmates respectively.

Wilper et al. (2009) applied NHANES-III age adjusted comparisons to SILJ and SISFCF data analyses to estimate hypertension prevalence in inmates. Contrary to the previous findings, prevalence was estimated to be lowest in the community population (25.6%). Within the correctional population, hypertension was estimated to be highest among state prison inmates (30.8%) and lowest in local jail inmates (27.9%).

Binswanger et al. (2009) also estimated hypertension prevalence to be lower in the community population. Estimated hypertension prevalence in the community population ranged from 6.9% in the 18 to 33 year old age group to 38.8% in the 50 to 65 group. Respectively, estimated prevalence was 10.3 and 49.7% among jail inmates and 10.6 and 50% in prison inmates. Following adjustment for race, education, United States birthplace, marital status, employment, and alcohol consumption, estimated prevalence in the correctional population remained higher than in the community (Binswanger et al., 2009, p. 914).

Coronary Vascular Disease and Dyslipidemia. Although the incidence of coronary vascular disease has been linked to preexisting diabetes, the development of T2D has been linked to preexisting coronary vascular disease (CVD) and dyslipidemia (ADA, 2011). Although research investigating the prevalence of dyslipidemia in the correctional population was not found in the literature, multiple researchers estimated the prevalence of cardiovascular disorders in inmates. Due to variations in the type of disorders studied and data collection methods, direct comparisons between prevalence estimates are limited.

As with their diabetes and hypertension findings, Hornung et al. (2002) estimated that the prevalence of heart disease prevalence was higher in community populations. Compared to the general community prevalence estimate of 6.03%, it was estimated that 3.2% of the total inmate population had heart disease. Prevalence was also predicted to be higher in community low SES population (8.8%) than the low SES inmate population (4.7%).

Based on SILJ self-report survey data, 5.9% of jail inmates were estimated to have a heart problem (Maraschak, 2006). Prevalence ranged between 4.4% in 24 or younger age group to 11.7% in those 45 years of age or older. According to SISFCF self-report survey findings, the overall prevalence estimate for heart disease in state and federal prison inmates was similar at 6.1 and 6.0% respectively (BJS, 2007). Among prison inmates, heart disease prevalence was estimated to increase with age and be higher in state prison inmates over 45 years of age (13.3%) than federal prison inmates in the same age group (12.8%).

Wilper et al. (2009) estimated myocardial infarction prevalence in inmates by applying age-adjusted comparisons to SILJ and SISFCF data analyses in the same manner used in their diabetes and hypertension research. These researchers determined that compared to the 3% estimated prevalence in community, federal and jail inmates had significantly higher prevalence

rates at 4.5% and 5.7% respectively. History of myocardial infarction prevalence was estimated to be lowest among local jail inmates (2.1%).

Binswanger et al. (2009) compared the estimated prevalence of cardiovascular disease/angina and heart attack/myocardial infarction between community, jail inmate, and prison inmate populations. Again, sample data from SILJ and SISFCF were analyzed to estimate prevalence in local jail and prison populations, and NHIS-SAF was used as the reference sample for the community population. Prevalence of cardiovascular disease/angina was predicted to increase with age across all populations and was found to be highest (4.2%) in the uppermost age group (50 to 65). Prevalence in this age group was estimated to be lower in the community (3.9%) and higher among local jail inmates (4.2%). As with cardiovascular disease/angina estimates, heart attack/myocardial infarction was predicted to increase with age across all populations and was found highest in the 50 to 65-year-old age group. Again, prevalence was estimated to be lower in the community (4.6%) and highest in local jail inmates (6.9%).

Impaired Fasting Glucose (Prediabetes). Persons with impaired fasting glucose (110-125 mg/dL), also called prediabetes, are at increased risk for developing T2D. Only one investigation was found to have reported impaired fasting glucose (IFG) estimates in the correctional population. Using a projection model that applied inmate demographic statistics to the NHANES-III community population reference standard, Hornung et al. (2002) estimated the prevalence of IFG in correctional settings. As had been done in the development of diabetes prevalence estimates, a second analysis was done to estimate IFG prevalence in the low SES subgroup.

Hornung et al. (2002) projected that 7.3% of the community population and 5% of the total inmate population had IFG. Comparing prevalence between correctional settings, it was

estimated that 6.9% of federal prison, 4.8% of state prison, and 4.3% of local jail inmates had IFG. Contrary to the higher diabetes prevalence rate that had been projected for the low SES group, IFG prevalence was not estimated to be appreciably different between community and correctional populations. Prevalence projections of IFG for the low SES community and correctional groups were estimated at 7% and 5.2% respectively. Within the low SES correctional group, 6.9% of federal prison, 4.9% of state prison, and 4.4% of local jail inmates were estimated to have IFG.

Physical Inactivity. Physical inactivity is an independent biophysical risk factor for T2D (Pederson, 2009; Stewart et al., 2005). Due to the restricted nature of correctional settings, the type, duration, and frequency of physical activity is limited (Leddy, Schulkin, and Power, 2009). There is no standardization and variation as what might be allowed is primarily dependent on safety and security requirements. A review of 10 court decisions involving quantity of exercise noted that judgments usually favored the one-hour-per-day five times a week permitted by numerous correctional settings (Lee, 1996, p. 175). Judgments concerning the quality (n=8) and location (n=8) of activities were incongruent but generally found that prisoners did not have a right to a specified activity type or setting (Lee, 1996). An updated review of a larger number of court decisions would provide more current information on exercise allowances in correctional settings.

Physical activity is further limited in older inmates with physical limitations who are unable to participate in available exercise options. Almost 45% of prisoners over 50 years of age and 82% of those over 65 estimated to have chronic physical limitations (Sterns, Lax, Sed, Keohane, and Sterns, 2008). With the aging inmate population this diabetes risk factor is likely to become increasingly significant.

Race. Individuals of African American, Hispanic/Latino, American Indian or Native Alaskan, Hawaiian or Pacific Islander, or Asian descent are at greater risk for T2D (ADA, 2011). Based on 2009 U.S. Census Bureau data the composition of racial/ethnic minority groups for the total national population was: African American, 12.9%; Hispanic/Latino, 15.8 %; Asian, 4.6%; American Indian or Alaskan Native, 1.0% ; and Native Hawaiian or Pacific Islander, 0.2% (U.S. Census Bureau, 2010). Based on 2009 BJS estimates, approximately 42% of sentenced prison inmates were African American and 22% were Hispanic/Latino (West, Sabol, and Greenman, 2010).. Although BJS did not report data for other racial/ethnic groups at greater risk for T2D risk, comparing reported estimates against those of the U.S. Census, percentages of racial/ethnic minorities in the national correctional system were greater than those of the total national population.

The estimated 2009 racial/ethnic minority group total reported by BJS was approximately the same as that reported by BJS 2002. At that time, it was estimated that approximately 45% of sentenced prison inmates were African American and 18% were Hispanic/Latino (Harrison and Beck, 2003). As in 2009, BJS did not report statistics specific to the American Indian or Alaskan Native, Hawaiian or Pacific Islander, or Asian populations for 2002.

Cost-Effectiveness

Several studies have studied the cost-effectiveness of targeted diabetes screening. Using a simulation model to estimate costs and consequences of screening current and former United States inmates at risk for diabetes and hypertension annually over twenty years, and intensive treatment of those diagnosed, cost-effectiveness was estimated (Tomlinson et al., 2002, p. 141-142). Prevalence and duration estimates were based on NHANES-III data, diabetes incidence on Centers for Disease Control (CDC) data, and co-morbidity estimates on data reported in

research conducted by disease specialty organizations. It was estimated that the annual cost of combined hypertension and diabetes screening would not exceed \$15 per person and the average annual cost of aggressive diabetes care per inmate was \$1,983. Expenditure predictions for combined hypertension and diabetes screening and aggressive diabetes care over twenty years for the population studied were \$204,817,860 and \$2,822,545,288 respectively (Tomlinson et al., 2002, p. 152-153). As it was assumed that the average inmate length of incarceration was 4.5 years, it was estimated that 63 percent of the diabetes costs, 82 percent of diabetes treatment costs, and 75 percent of hypertension treatment costs would be incurred following incarceration (Tomlinson et al., 2002, p. 150 and 153). Early disease identification through screening, aggressive disease management, and patient adherence to treatment during and following incarceration were predicted to decrease morbidity and increase life expectancy. Through these interventions, it was estimated that 386,108 additional person-years would be attained for this population over 20 years, with the majority of time predicted to be spent outside of prison (Tomlinson et al., 2002, p. 152).

Based on prospective United Kingdom diabetes screening cost data, a Markov model was used to estimate the cost-effectiveness of one-time diabetes screening against no screening in the U.S. population. Diabetes screening targeted to those with hypertension was compared to universal diabetes screening. Cost-effectiveness ratios based on quality adjusted life years (QALY) were calculated incrementally by decade starting at age 35 and ending at age 75. Estimated QALY for diabetes screening of those with hypertension who received intensive control of diabetes and hypertension following diabetes diagnosis per decade was 0.08, 0.16, 0.22, 0.23, and 0.18 (Hoerger et al., 2004, p. 692). Comparatively, QALY estimates for universal screening followed by intensive control of diabetes and hypertension following

diabetes diagnosis were lower at 0.05, 0.05, 0.11, 0.11, and 0.11 respectively (Hoerger et al., 2004, p. 694).

Cost estimates were based on quality adjusted life years (QALY) and reported in 1997 United States dollars. The estimated cost to the U. S. healthcare system per QALY for targeted screening ranged from \$87,096 at age 35 to \$32,106 at age 75. Targeted screening was found to be more cost-effective than universal screening estimates which ranged from \$143,839 at age 35 to \$443,433 at age 75. Targeted screening was estimated to be most cost-effective for ages 55 and greater (range: \$34,375 to \$32,106) and more cost-effective than universal screening across the same age groups (\$360, 966 to \$443,433) (Hoerger et al., 2004, p. 695-697).

Chatterjee, et al. (2013) studied the cost-savings of screening against no screening in a sample of 1,573 subjects.) Costs of five non-fasting screening tests (random plasma glucose [RPG], random capillary glucose [RCG], glycated hemoglobin [HgbA1c], random plasma/capillary glucose [GCTpl] and random capillary glucose [GCTcap] one hour after a 50 gram glucose challenge) were calculated (p. 1). Screening expenditures were based on Medicare reimbursement tables and estimated for a three year period. Costs included direct screening expenditures, oral glucose tolerance testing (OGTT) done subsequent to findings suggestive of diabetes, and direct medical costs of diabetes diagnosed through testing, and false-negative test results. Costs were also determined for no screening, universal screening, and screening targeted to those at high risk. High risk factors in men included age >55 , BMI > 35 , SBP ≥ 130 , serum triglycerides ≥ 150 , HDL <40 , and family history of diabetes.

Regardless of the type screening test, universal screening was found to be more cost effective than no screening. The overall health system costs for screening and treatment of diabetes of the 1,573 subjects by risk factor ranged from \$67,838 using RPG testing to \$81,467

using HgbA1c. In comparison, the cost of not screening was \$95,710. Targeted diabetes screening was found to be more cost-effective than universal screening. Screening was found to be most cost-effective in those with a BMI of >35 (range \$24,103 using GCTpl to \$28,018 using RCG), SBP ≥ 130 (range \$26,519 using GCTpl to \$32,543 using HgbA1c), and age >55 (range \$26,165 using GCTpl to \$34,722 using HgbA1c) (Chatterjee, et al. 2013).

Summary

This review of the literature examined research pertaining to theoretical and empirical support of T2D screening and empirical evidence reporting the prevalence of T2D and selected major risk factors within the correctional population. WHO (2003) justifications for T2D screening are congruent with Leavell and Clark's (1953) Preventive Medicine framework and Healthy People 2020 objectives (U. S. Department of Health and Human Services, 2010). Screening justifications were supported by DPP and DPOS findings which found T2D risk and incidence decreased in obese pre-diabetics who adhered to lifestyle intervention or Metformin therapy (Perreault, 2012; DPPRG, 2012). These findings may be useful to support ongoing T2D screening and interventions to decrease T2D risk in correctional settings having similar racial ethnic inmate characteristics.

In contrast to the DPP and DPOS findings, the European ADDITION studies did find that outcomes had significantly improved with intensive management of screen-detected diabetes as compared to usual care (Charles, et al., 2013; Simmons et al., 2012; Griffin et al., 2011). The benefits of intensive or usual care against no care could not be quantified and it is not known if findings would have varied in a population racial/ethnic group that was not predominantly Caucasian (95%). Based on 2009 racial/ethnicity data reported by the National Bureau of Justice (BJS), the total percentage of inmates belonging to high risk T2D racial/ethnic groups (64%)

(West et al., 2010). For these reasons ADDITION study findings should be interpreted cautiously by United States correctional systems with inmate population characteristics different from ADDITION samples.

Using prevalence projection modeling and incorporating data from the 1994 NHANES-III survey, 1990 U.S. Census, and 1995 NIJ inmate population estimates, Hornung, et al., (2002) reported that prevalence of diabetes, impaired fasting glucose (prediabetes) and heart disease were estimated to be lower in correctional settings compared to the community. In contrast, Bureau of Justice SILJ (2002) and SISFCF (2004) survey findings reported that more inmates age 45 and older were incarcerated in prisons than jails. It was also estimated that prevalence of diabetes, hypertension, heart disease, and dyslipidemia was greater in older inmates and in prison settings. These and other BJS survey data were subsequently used by other researchers to estimate prevalence and make prevalence projections.

Maraschuk (2006) extracted data from the BJS surveys and reported that hypertension and heart disease increased with aging and was greater among prison inmates age 45 or more. Applying age-standardization to prevalence data derived from SILJ, SISFCF, and NHANES-III surveys, data, Wilper, et al. (2009) estimated that the prevalence of diabetes, hypertension, and myocardial infarction was higher among prison and jail inmates. In their prevalence study based on SILJ, SISFCF, and NHIS-SAF data, Binswanger et al. (2009) reported that prevalence estimates for hypertension were estimated to be increased in prison and jail inmates, following adjustments based on race/ethnicity and other factors, diabetes and myocardial infarction prevalence was similar between correctional and community populations. Differences between reported estimates may reflect intervals between time studies had been conducted or due to variations in surveys used to make projections or data analysis. Despite differences between

these and other estimated prevalence findings, major risk factor data may help understand the potential risk for T2D onset in correctional populations as well as its potential impact on correctional and community systems.

Based on a simulation model Tomlinson et al. (2002) predicted that T2D screening might decrease T2D related morbidity and costs among current and former inmates, with the majority of savings being realized following incarceration. Chatterjee et al. (2010) and Hoerger et al. (2004) reported that cost savings may also be achieved through targeted T2D screening which reduces the number of unnecessary screening tests. Apart from targeting T2D screening to identified high risk factors, Gillies et al. (2008) found that screening targeted to those age 45 and older who at average risk of developing T2D was beneficial. These cost savings findings support the benefit of targeted screening in correctional systems.

Chapter Three

This quality improvement pilot project used a retrospective descriptive study design to describe the number and frequency of selected major T2D risk factors in a sample of inmates diagnosed with T2D during incarceration. This methods chapter discusses the plan whereby permission was granted to conduct the project, the sample was obtained, data was collected, and findings were reviewed. The chapter has the following sections: 1) population and sample; 2) design, 3) data collection instrument development; 4) institutional approval; 5) data collection; 6) data analysis; 7) generalization and predictions; and 8) summary.

Population and Sample

On January 1, 2011, the state system's total inmate population was approximately 17,000. It was not known how many of these inmates had T2D prior to incarceration or how many were diagnosed with T2D during incarceration. Based on information from the existing electronic pharmacy database reporting the number of inmates taking oral medications commonly used to treat T2D, it was estimated that approximately 450 adult male, less than 20 female, and less than 5 juvenile male inmates within the correctional system might have T2D. As the estimated sample sizes of female juvenile or adult inmates and male juvenile inmates with T2D were deemed too small to benefit the selection of a screening guideline for statewide implementation, these populations were excluded from this project.

Inclusion criteria. For the purposes of this quality improvement pilot project, the sample was limited to male inmates who were age 18 and older and had been diagnosed with T2D during incarceration within the state correctional system.

Exclusion criteria. Adult male inmates who were diagnosed with T2D before incarceration and those having a diagnosis of Type 1 diabetes, were excluded from the sample.

Also excluded from the sample were juvenile male (age 17 and younger) and female (any age) inmates.

Sample size. The sample for this pilot project consisted of 50 subjects. In consultation with a doctorally-prepared statistician, this sample size was deemed adequate for this pilot project as a descriptive design was planned (R. Feinn, personal communication, July 22, 2011). Power analysis was deemed irrelevant as statistical inference testing was not planned (R. Feinn, personal communication, July 22, 2011). At the time the sample size was set, it was not known as to how many inmates might meet inclusion criteria or how many health records might need to be reviewed to identify 50 subjects. Given this, it was anticipated that health records belonging to inmates from at least several correctional facilities would need to be reviewed to attain the sample size. Surprisingly, the review of 123 inmate health records, at one facility, of those who potentially met inclusion criteria yielded 50 subjects.

After the sample size for the pilot project had been met, a negative binomial distribution analysis was performed to estimate the prevalence rate of T2D diagnosed during incarceration ($n=50$) within the sample of inmates whose health records were reviewed ($n=123$) and not discarded ($n=3$) (S. J. Walsh, personal communication, April 21, 2013). Based on this analysis, 40.2% of the inmates whose records were reviewed had T2D diagnosed during incarceration. Applying an approximated standard error magnitude of less than 4.3% the statistician determined that the confidence interval for the estimated prevalence rate was: (31.8%, 48.6). It was further noted that based on the initial goal of finding 50 subjects for this pilot study, the properties of negative binomial distribution guaranteed that the standard error for the estimated prevalence rate would have been relatively precise regardless of the number ($n=123$) of records reviewed (S. J. Walsh, personal communication, April 21, 2013).

Design

This quality improvement pilot project was implemented for the purpose of answering two study questions:

1. What is the number and frequency of selected preexisting major T2D risk factors in a sample of adult male inmates diagnosed with diabetes during incarceration within one state correctional system?
2. Which correctional diabetes guideline screening recommendations best addresses T2D risk in the sample?

In response to the first question, a retrospective descriptive design was used to describe the number and frequency of preexisting selected major T2D risk factors in a sample of adult male inmates diagnosed with T2D during incarceration within one state correctional facility. In response to the second question, expert opinion was deemed essential to generating recommendations from a clinical risk and benefit perspective (Asch et al, 2011).

Based on their clinical expertise and familiarity with the correctional population, a clinical panel was formed to review the project's findings. The group consisted of the medical directors of the correctional system and the contracted health care provider and a community-based certified diabetes educator with expertise in treating inmates following incarceration. This group was tasked to review pilot project data against guideline screening recommendations and decide which guideline best addressed T2D risk in the sample.

Instrument Development

A data collection instrument was developed specifically for this project to collect selected major T2D risk factor data and related information contained within the inmate health record. Individual instrument item content was reviewed by the medical directors of the correctional system and the contracted health care provider to ensure congruence with the purpose of the pilot

project and also to validate that item content clearly and accurately reflected the elements for which data was to be collected. Risk factor information corresponded with those of T2D guideline screening recommendations being considered for implementation. In addition to documentation of selected risk factor information for data collection purposes, documentation of demographic data and diabetes diagnostic information also served to facilitate the sample selection process by helping to eliminate inmates who did not meet pilot project inclusion criteria (Appendix A). The instrument was also designed to collect information regarding the length of time between incarceration and T2D and the number of facilities in which an inmate was housed prior to diagnosis. This information was requested by the Department of Correction to help plan future inmate education programs to address reversible T2D risk factors.

Clinical Guidelines. Type 2 Diabetes (T2D) screening recommendations considered for this pilot project were embedded within three diabetes management guidelines used in United States correction systems: Diabetes Management in Correctional Institutions (ADA, 2011b), National Commission on Correctional Health Care (NCCHC) Diabetes Guideline for Disease Management in Correctional Settings (2009), and Federal Bureau of Prisons (FBOP) Diabetes Clinical Practice Guidelines (2010). The recommendations within each of these guidelines advocated screening of those at high risk for developing the disease. However, major risk factors for which screening was recommended varied between guidelines.

Diabetes Management in Correctional Institutions was developed by the American Diabetes Association (ADA, 2011b) and conformed to its Standards of Medical Care in Diabetes used in the community (ADA, 2011a). Based on those standards, T2D would be considered in those with a BMI of 25 or greater and with at least one additional major T2D risk factor. Major risk factors in adult male populations also included: high-risk race/ethnicity (African American/black, Hispanic/Latino, Asian American/Asian, Native North American, or Pacific

Islander); current antihypertensive therapy or blood pressure of 140/90 or more; dyslipidemia (HDL cholesterol level < 35 mg/dL and/or triglyceride level > 250/dL); cardiovascular disease; physical inactivity; first-degree relative with diabetes; and history of impaired fasting glucose (prediabetes) as measured by elevations in glycosylated hemoglobin (HgbA1c) of 5.7 to 6.4 or fasting blood glucose (FBG) of 110 to 125 mg/dL measurements (ADA, 2010, p. S12). In absence of any of the major risk factors, the ADA advised T2D screening of those who are 45 of age or more (ADA, 2011a, p. S13).

The diabetes management guideline issued by the National Commission on Correctional Health Care in 2009 was adapted from prior ADA guidelines (ADA, 2008a, 2008b). At a minimum, T2D screening was recommended for inmates with a BMI >25, history of hypertension or elevated cholesterol, or age 45 or older (NCCHC, 2009, p. 1). As these risk factors were taken from the ADA guidelines, risk factor criteria were identical.

Conversely, 2010 Federal Bureau of Prisons (FBOP, 2010) diabetes practice guidelines were based on prior U.S. Preventive Services Task Force recommendations and advised routine diabetes screening only for low-risk inmates who have a treated or untreated blood pressure greater than 135/80. Otherwise, these guidelines recommend that T2D screening should be targeted to inmates with dyslipidemia or other disease states as clinically appropriate (FBOP, 2010; USPSTF, 2008).

The ADA and FBOP advised annual testing of those identified with impaired fasting glucose (prediabetes) on initial screening (ADA, 2011a, 2011b; FBOP, 2010). For those with other major T2D risk factors, repeat screening at 3-year intervals was recommended (ADA, 2011a, 2011b; FBOP, 2010). The 2009 NCCHC guideline referred to prior ADA recommendations for guidance (ADA, 2008a, 2008b).

Data Collection Instrument. As national correctional guidelines varied in regards to which T2D risk factors should be considered in screening inmates, major risk factors named in one or more guidelines, routinely documented in the health record, and retrievable by the investigator were selected for data collection and listed on the instrument. As data pertaining to other major T2D risk factors - specifically physical inactivity, first-degree relative with diabetes, acanthosis nigricans - were not collected for this pilot project, these risk factors will be added to future studies. In addition, major T2D risk factor data specific to females (i.e. history of gestational diabetes, polycystic ovarian disease, or having delivered a baby weighing > 9 pounds) will be obtained in studies involving female inmates.

Demographic information collected for risk factor screening purposes consisted of race/ethnicity, height and weight (which were used to measure BMI), and age at the time of T2D diagnosis. The instrument addressed whether or not, based on the collected information, the inmate had risk factors for T2D based on race/ethnicity (belonging to a high risk racial/ethnic group – African American (Black), Hispanic/Latino, Native North American, or Asian), weight (BMI of 25 or more), or age (45 or older).

As BMI was not routinely assessed or reported in the health record, but could be determined using the last recorded height and weight documented prior to T2D diagnosis, BMI was calculated using a standard graph (Appendix B).

The form also provided for the collection of demographic content that could be useful to plan future inmate education programs to address reversible T2D risk factors. For the purposes of this project, date of incarceration was defined as the initial date (month and year) of incarceration to the state correctional system inclusive of any subsequent returns from escape or transient out-of-state or federal custody compacts that might have occurred. Date of T2D

diagnosis was defined as the date the correctional physician, nurse practitioner, or physician assistant documented the condition in the inmate health record. The measured length of incarceration prior to T2D diagnosis was inclusive of the date (month and year) of incarceration and the date (month and year) of diagnosis. The number of facilities in which health care had been provided during the incarceration period in which T2D was diagnosed was inclusive of the facility where the inmate was admitted to the correctional system. This information was obtained through the review of problem lists, clinical notes, transfer summaries, infirmary records, laboratory records, or other health provider documentation contained within the inmate health record.

Historical medical information was limited to selected major T2D risk factors that were evident prior to T2D diagnosis, included on the diabetes guidelines, and documented in the health record, in particular, history of impaired fasting glucose or prediabetes as measured by elevations in glycosylated hemoglobin (HgbA1c) of 5.7 to 6.4 or fasting blood glucose (FBG) of 110 to 125 mg/dl measurements (ADA 2011, 2012). History of coronary vascular disease, prescribed lipid lowering therapy, fasting high density lipoprotein (HDL) of ≤ 35 , or fasting serum triglyceride (FST) of ≥ 250 or more were noted. Prescribed antihypertensive therapy, most recent documented systolic blood pressure (SBP) measurement of ≥ 140 mm/Hg or diastolic blood pressure of ≥ 90 mm/Hg, or history of three or more consecutive treated or untreated SBP measurements > 135 mm/Hg or DBP measurements > 80 mm/Hg were additional T2D risk factors named on the instrument.

Prior to submission to the correction system Research Advisory Committee (RAC) and the Internal Review Board (IRB) of the contracted health care provider, the instrument was reviewed by the contracted health provider's medical director and the statistician. This was done

to assure that demographic information and labeling of selected major T2D risk factors named in one or more of the screening guidelines was clear, concise, and complete and contained no identifying subject information. A recommendation by the statistician to eliminate several duplicative data elements was followed. Subsequent to this, and prior to implementation, the instrument was reviewed by members of the RAC and IRB committees. An IRB recommendation to use a list of simple ordinal numbers (1, 2, 3 ...) instead of a random number table for subject identification was made.

Institutional Approval

Approval to conduct this quality improvement pilot project was obtained from the Research Advisory Committee (RAC) of the correctional system. Following RAC approval, institutional approval was obtained from the Internal Review Board (IRB) of the contracted healthcare provider. Both approval documents were thereafter sent to the University of Connecticut IRB for its review and approval. Project modification was granted by the contracted healthcare IRB, and reciprocal approval was granted by the University of Connecticut IRB (IRB Number: 12-027S-2). Project continuation was granted by the contracted healthcare IRB, with reciprocal approval by the University of Connecticut IRB.

Protection Against and Minimization of Risks. This quality improvement pilot project consisted of non-experimental procedures (retrospective health record reviews) minimizing risks to subjects. Alternative options had included experimental testing, specifically fasting blood glucose (FBG) or two-hour oral glucose tolerance testing (OGTT). Risks of FBG screening included discomfort and potential for trauma/infection associated with phlebotomy. Risks of OGTT screening included safety and security issues associated with changes in custody routine to accommodate the testing period and costs to inmate workers who would have been unable to

work for the hours or the day of testing. Expenditures (FBG = \$23 per test; OGTT = \$36 per test) associated with testing analysis would have been difficult to justify in cases of normal test results (Healthcare Blue Book, 2013).

Protections pertaining to prisoners as subjects. The nature and scope of this quality improvement pilot project limited its findings to the correctional facility where the sample was obtained. As there was no experimental testing, risks to subjects were minimal. As the project was limited to the review of health records of inmates diagnosed with T2D during incarceration, the findings of this project have the potential to benefit other inmates who might be at risk for the disease and could benefit from early diabetes detection and health education. Timely and appropriate T2D management and health promotion activities may decrease overall department health care costs and benefit the community at large.

As confidentiality and risk for protected health information disclosure need to be protected in both inmate and community populations, the risks involved in this project were commensurate with those that would have been accepted by non-prisoner volunteers. De-identified data from inmate health records was collected by the researcher as necessary for this project. Prison authorities had no involvement in health record selection or access to the data collection instruments, logbook, or IBM SPSS database.

Procedure

Protection of Privacy. The privacy of subjects was protected through the implementation of procedure whereby data were not linked to identifying subject information. Prior to data collection, copies of the instrument were made. Each copy of the instrument form had a preprinted subject number according to a list of simple ordinal numbers (1, 2, 3 ...). As

such, the subject number was not linked to inmate name, date of birth, inmate identification number, housing unit, or social security number.

Confidentiality of Data. Measures to protect the confidentiality of data were implemented. The list of subject numbers was recorded in a bound logbook and locked in a file cabinet within a locked office located on the campus of the contracted health care organization and accessible only to the dissertation advisor and researcher. The preprinted instruments with subject numbers were kept in a stack according to numerical order as documented in the logbook. These were kept in the possession of the researcher during transportation between external sites and the office.

Instruments were retained in a secure University of Connecticut Health Center (UCHC) location and accessible only to the dissertation advisor and researcher. Following the dissertation project, the logbook will be destroyed. The instruments will be retained in a secure UCHC location for a minimum of three years following project completion. Destruction of the logbook and instruments will consist of document-shredding and disposal through the contracted health care organization's existing system of confidential destruction process of secure document shredding. Data were entered into an IBM SPSS spreadsheet of a password-protected desktop computer. Access to recorded electronic (IBM SPSS) data was limited to the dissertation advisor, researcher, and statistician. Following the doctoral dissertation presentation, electronic files of spreadsheets will be deleted. Any hard copies of files that might have been made will be stored with project instruments and follow instrument retention and destruction processes as previously outlined.

Data Management

Data Collection. Data collection followed a systematic process whereby correctional facilities were ranked according to the number of adult male inmates estimated to have T2D. Estimates of facility T2D prevalence consisted of the review of an on-demand electronic pharmaceutical database report completed prior to project approval.

The electronic pharmaceutical database reported medications filled by the central pharmacy unit in response to prescriber orders faxed to the pharmacy by facility nursing staff. As facility automated dispensing units (ADUs) were linked to the pharmacy system, medications removed by nurses from ADUs were also reported. Database information included inmate number, inmate name, facility, housing unit, generic medication name, medication dose and frequency, first pharmacy fill, last pharmacy fill, medication prescriber, and medication category. This information applied to single-dose, episodic, and chronic medications.

The pharmacy filled medication orders, including oral medications commonly used to treat T2D, individually and based on specific inmate information. In addition to orders filled by the pharmacy, a limited supply of medications was stocked in ADUs. The ADUs were used to supply medications for urgent needs or in advance of orders received from the pharmacy. Nurses were required to sign out each medication taken from the ADU inventory by individual inmate. The ADU inventory was directly linked to the electronic pharmaceutical database.

The pharmacy supplied insulin to facilities as an ADU stock medication. When multi-dose vials were taken from ADU inventory, nurses signed out the total number of vials used using a facility identifier. As usage was not linked to particular inmates, the pharmacy database could not be used to obtain an accurate reporting of individual inmate insulin usage. Therefore, the number of inmates who might currently be administered insulin as sole or part of their T2D treatment could not be estimated.

As the electronic database could not be linked to insulin use, the generated pharmaceutical database report was limited to inmates currently prescribed oral medications commonly used to treat T2D. Based on this report, approximately 450 inmates could have had T2D. However, it is possible that medication might have been ordered to treat disorders other than T2D. As no tracking system existed to link medications with diagnoses, the only way to determine if medications had been ordered for the management of T2D was to individually review the paper health records of inmates prescribed these medications.

As it was not known exactly how many inmates within the correctional system had been diagnosed with T2D during incarceration, it was important to identify as many potential subjects as possible prior to conducting data collection. To verify potential subjects that had been listed on the on-demand pharmacy report and identify additional potential subjects that may have not yet been included on the pharmacy report, Medication Administration Records (MARs) of all inmates prescribed medication and housed within the facility sampled were reviewed. As MARs accompany inmates to their receiving facilities when they are transferred, and are updated following the receipt of new, adjusted, or discontinued medication orders, facility nursing supervisors and staff nurses regularly assigned to the facility pharmacy deemed that the information documented on MARs was the most current and accurate source of medication orders.

The review of MARs commenced at the facility ranked highest in probability based on the prevalence estimates derived from the pharmaceutical database report. As inmates currently prescribed medications commonly used to treat T2D were detected, the individual inmate identification numbers were entered into a bound logbook to correspond with a prepared list of simple ordinal numbers (1, 2, 3 ...). The ordinal numbers were assigned to subjects in

numerical order. As such, the subject number was not related to inmate name, date of birth, inmate identification number, housing unit, or social security number. The bound logbook was locked in a file cabinet in a locked office of UCHC and accessible only to the student researcher and faculty advisor (principal investigator). The logbook was retained for the duration of the project including data analysis and presentation of the doctoral dissertation.

Prior to data collection, copies of the data collection instrument were made and numbered with simple ordinal numbers to correspond with each inmate identification number noted in the logbook. The preprinted instruments with subject numbers were kept in a stack according to numerical order as documented in the logbook.

Data were collected through the review of health records corresponding to those of inmates recorded in the logbook and the prepared collection instruments. If health record information needed to complete the demographic data elements listed on the instrument was missing, the data were to be discarded and another health record reviewed to replace it.

Based on the review of MARs at the highest-ranking facility, 232 inmates were identified as currently taking medications commonly used to treat T2D. The sample of 50 subjects was derived from the review of 123 health records belonging to potential subjects. If it had been found that the sample size 50 had not been attained at the highest-ranking facility, the process would have proceeded at the next likely facility. This method would continue at subsequent facilities until the established sample size had been met or all health records of inmates identified to be taking medications commonly used to treat T2D had been reviewed.

Data Cleansing. Data were entered into an IBM SPSS spreadsheet on a continuous basis. Each entry was double-checked against the data collection instrument for accuracy.

The sample of 50 subjects was derived from the review of 123 health records of potential subjects. Through the review of health records, 9 subjects were found to meet project inclusion criteria during the first week of data collection, 25 during the second week, and 19 during the third week for a total of 53. Although the number of subjects meeting criteria was tracked on an ongoing basis to monitor the status of data collection for the established sample size of 50 subjects, it was not until data for the third week were tabulated was it noted that data from 3 additional potential subjects had been obtained. It was decided to retain these forms in the event that reexamination of the last week's data found that any of the data collection forms were missing demographic data, and therefore could not be used. Reexamination found that it was not possible to calculate one subject's BMI as his weight exceeded the limits of the standard graph (Appendix B). All data for this subject were discarded and replaced with that of the 51st subject. Due to over-collection, the 52nd and 53rd potential subjects were discarded.

Data Analysis. Type 2 diabetes risk factor analysis was performed using IBM SPSS, version 19. Only data of inmates who met project criteria (adult males diagnosed with T2D during incarceration) as identified on the review of health records and had complete demographic data were entered into the IBM SPSS database and analyzed. Information entered into the data and variable views of the IBM SPSS project file were checked against the raw data to ensure that errors in data entry had not been made.

Data were analyzed to measure the number and frequency of selected preexisting major T2D risk factors in adult male inmates diagnosed with T2D during incarceration. Analyses were done to estimate the number of those with T2D who had been diagnosed during incarceration and to describe relationships between the incidence of T2D risk factors and the variables of race/ethnicity, BMI, and age.

Generalization and Predictions

As sampling was limited to one facility, the findings of this quality improvement pilot project cannot be generalized and are therefore limited to the facility where data was obtained. Following the completion of data collection and analysis, a clinical panel convened to review these findings against the 2009 NCCHC, 2011 ADA , and 2010 FBOP diabetes guideline screening recommendations to decide which guideline best addressed T2D risk in the sample.

Summary

Type 2 diabetes screening recommendations in correctional settings differ according to major risk factor criteria. The guideline that recommends screening of those with risk factors most commonly associated with disease development within a population would be most appropriate to target screening. Data concerning the number and frequency of known major T2D risk factors identified within a sample of inmates diagnosed during incarceration were collected and described to help facilitate guideline selection and standardize screening within a state correctional system. By doing so, a clinical panel subsequently proposed a guideline for implementation as a prospective quality improvement study.

Chapter 4

The findings of this quality improvement pilot project are reported in this chapter. The method of data analysis was guided by the project's research questions, which was to initially

describe the number and frequency of preexisting major T2D risk factors in a sample of adult male inmates diagnosed with diabetes during incarceration and to subsequently decide which diabetes guideline screening recommendations best addressed T2D risk in the sample.

Results

Fifty subjects were obtained from the review of 123 health records, excluding 3 health records corresponding to potential subjects whose data were discarded. Descriptive characteristics of the sample's demographic variables are presented in Table 1.

When this pilot project was conducted, approximately 31% of the adult male population at the project facility was > 45 years of age. Subject age at the time of T2D diagnosis ranged from 23 to 66 years of age, with the mean age at the time of diagnosis 45.64 (SD 11.07). Twenty-two (44%) subjects were black, sixteen (32%) were Hispanic/Latino, and twelve (24%) were white. No subjects were identified as belonging to Asian, Native North American, or Other racial/ethnic groups. Based on the most recent measured height and weight that had been documented prior to T2D diagnosis, the sample had a mean BMI of 30.54 (SD 5.85), ranging from 21 to 49. Forty-three subjects (86%) had a BMI > 25.

The date of incarceration for which T2D diagnosis was made ranged from June 1983 to April 2011. The mean length of incarceration prior to T2D diagnosis was 37.96 months (SD 60.91), and ranged from 1 to 283 months. Twenty-three (46%) subjects were diagnosed within 12 months of incarceration, fourteen (28%) between 14 and 27 months, eight between 34 and 88 months (16%), and five between 134 and 283 months (10%). The average number of facilities in which health care was provided during the incarceration period prior to T2D diagnosis was 3.32 (SD 2.98) and ranged between one and seventeen.

Table 1

Demographics (N=50).

<u>Characteristic</u>	<u>Mean</u>	<u>SD</u>	<u>95% CI for Mean</u>	<u>Median</u>	<u>Range</u>
Age	45.64	11.07	42.50-48.78	44.50	23-66
BMI	30.54	5.85	28.88-32.20	29.50	21-49
Months Until Diagnosis	35.74	58.36	19.15-52.33	15.00	1-283
Number of Facilities	3.32	2.98	2.47-4.17	2.00	1-17
<u>Race/Ethnicity</u>	<u>Frequency</u>	<u>Percent</u>			
Black	22	44.00			
Hispanic/Latino	16	32.00			
White	12	24.00			
Asian	0	0.00			
Native American	0	0.00			
Other	0	0.00			

Descriptive characteristics of the T2D risk factor variables are presented in Table 2.

A total of thirteen (26%) diabetics were found to have a preexisting history of impaired fasting glucose (prediabetes). Thirteen had been identified through a calculated fasting blood glucose (FBG) measurement of 110 to 125 mg/dl. Of these, only three subjects had concurrent glycosylated hemoglobin (HgbA1c) testing. HgbA1c results for these subjects ranged from 5.7

to 6.4. No subjects were identified as having HgbA1c testing in the absence of concurrent FBG testing.

Nine (18%) subjects were found to have a preexisting history of dyslipidemia. Of these, seven (14%) had been prescribed lipid lowering medication or had a high density lipoprotein (HDL) measurement ≤ 35 in addition to a fasting serum triglyceride level ≥ 250 , one (0.02%) had a fasting HDL without a fasting serum triglyceride level ≥ 250 , and one (0.02%) had a fasting serum triglyceride level ≥ 250 without a fasting HDL ≤ 35 .

Four (8%) subjects had a current or previous history of coronary vascular disease. Nineteen subjects (38%) met one or more diagnostic criteria for hypertension (medication therapy or most recent SBP ≥ 140 or DBP ≥ 90 with ≥ 3 consecutive measurements SBP 135 or DBP ≥ 80). Seventeen (34%) had a history of antihypertensive therapy, a most recent systolic blood pressure (SBP) measurement of ≥ 140 , or diastolic blood pressure (DBP) measurement of ≥ 90 . Four subjects (8%) had three or more consecutive treated or untreated SBP measurements of > 135 or DBP > 80 . Two subjects belonging to this elevated blood pressure group had been prescribed antihypertensive therapy.

Table 2

Type 2 Diabetes risk factors (N=50)

Risk Factor	Frequency	Percent
Age ≥ 45	27	54.00
BMI ≥ 25	43	86.00
Cardiovascular Disease	4	8.00
Dyslipidemia: Total	9	18.00
Fasting HDL ≤ 35 and Fasting Serum Triglycerides ≥ 250	7	14.00
Fasting HDL ≤ 35	1	0.02
Fasting Serum Triglycerides ≥ 250	1	0.02
High Risk Racial/Ethnic Group: Total		
Black, Hispanic/Latino, Native American, or Asian	38	76.00
Hypertension: Total	40	80.00
Most Recent SBP ≥ 140 or DBP ≥ 90 and ≥ 3 consecutive measurements SBP >135 or DBP ≥ 80	19	38.00
Most Recent SBP ≥ 140 or DBP ≥ 90	17	34.00
Three consecutive measurements SBP >135 or DBP ≥ 80)	4	8.00
Impaired Fasting Glucose (Prediabetes): Total	13	26.00
Fasting Blood Glucose: 110 - 125 and HgbA1c: 5.7 - 6.4	10	20.00
Fasting Blood Glucose: 110 – 125 without HgbA1c testing	0	0.00
HgbA1c: 5.7 - 6.4 without Fasting Blood Glucose testing)	3	6.00

Clinical Panel Findings

A clinical panel consisting of the medical directors of the correctional system and contracted health care provider and a community-based certified diabetes educator with expertise in treating inmates following incarceration met to review the T2D screening recommendations of the three guidelines and data from the pilot project. The three guidelines considered were: Diabetes Management in Correctional Institutions (ADA, 2011b), Federal Bureau of Prisons Diabetes Practice Guidelines (FBOP, 2010), and National Commission on Correctional Health Care Diabetes Management Guidelines (NCCHC, 2009).

Based on their review, the members of the clinical panel agreed that its selection of a guideline could be based on their review of the four most common T2D risk factors that had been identified: BMI ≥ 25 (86%; n=43), belonging to a high risk racial/ethnic group (76%; n=38), age ≥ 45 (54%; n=27), and a history of hypertensive medication therapy or a most recent SBP measurement of ≥ 140 or a DBP measurement of ≥ 90 (34%; n=17). The group also agreed that mean age (45.64) and BMI (30.54) at the time of T2D were important findings.

Clinical Guidelines

The Federal Bureau of Prisons Diabetes Practice Guidelines. The clinical panel reviewed the Federal Bureau of Prisons (FBOP, 2010) diabetes practice guidelines and rejected it for several reasons. These guidelines recommended routine diabetes screening only for low-risk inmates who have a treated or untreated blood pressure $> 135/80$. Otherwise, these guidelines advised T2D screening as part of the management of disease states as clinically appropriate (FBOP, 2010).

Based on the 2010 FBOP recommendation to screen asymptomatic inmates having treated or untreated SBP ≥ 135 or DBP ≥ 80 , only 8% (n=4) of subjects would have been screened for T2D. The panel deemed that based on this criterion alone, many inmates with T2D might not

be screened. The panel also felt that direction to conduct T2D screening as part of the management of disease states as clinically appropriate provided insufficient guidance to standardize screening within the state's correctional system.

The American Diabetes Association Standards of Care. The ADA's Diabetes Management in Correctional Institutions (ADA, 2011b) recommended conformity to the ADA Standards of Care. Based on these standards, screening in adult male inmates should be considered in those having a BMI of ≥ 25 and with at least one additional T2D risk factor: high-risk race/ethnicity, current antihypertensive therapy or blood pressure $\geq 140/90$, impaired fasting glucose/ prediabetes, dyslipidemia, cardiovascular disease, a first-degree relative with diabetes, or physical inactivity. In absence of any of the named risk factors, the ADA advises T2D screening for individuals ≥ 45 years of age (ADA, 2011a).

The clinical panel noted that 84% (n=42) of subjects in the sample would have been screened for T2D based on the BMI ≥ 25 with one additional risk factor criterion (Table 3). Dyslipidemia based on the 2010 ADA criterion of Fasting HDL ≤ 35 or Fasting Serum Triglycerides ≥ 250 was not a primary risk factor in the sample population with only 14% (n=7) of subjects found with a prior history. Although the group had expected that the findings would be more significant, only 26% (n=13) of subjects were found to have a history of impaired fasting blood glucose (prediabetes) based on ADA HgbA1c (5.7 - 6.4) or Fasting Blood Glucose: (110 – 125) criterion.

The clinical panel noted that data for major T2D risk factors named by ADA, primarily physical inactivity and first-degree relative with diabetes, had not been collected for this pilot project. It was explained this information was not collected as it had not been routinely documented in the health record by health care staff the data were unavailable. Subsequently, the

clinical panel decided to compare the remaining variables against the National Commission on Correctional Health Care (NCCHC, 2009) Diabetes Management Guidelines prior to making its recommendation.

The National Commission on Correctional Health Care Diabetes Management

Guidelines. In comparison to the ADA which recommends T2D screening for those having another major T2D risk factor in addition to BMI ≥ 25 , the National Commission on Correctional Health Care (NCCHC, 2009) guideline allowed for screening based on individual major risk factors. The diabetes management guideline issued by NCCHC recommended routine T2D screening for inmates having at least one T2D risk factor. Major T2D risk factors included overweight/obese (BMI ≥ 25), history of hypertension or dyslipidemia, and age 45 or more (NCCHC, 2009, p.1). NCCHC criteria for hypertension and dyslipidemia were the same as those of the ADA.

Applying 2009 NCCHC criteria to the major T2D risk factors described, 98% (n=49) of the sample subjects would have been identified for screening. Comparatively, the number of those who would have been identified for T2D screening using ADA criteria (84%, n=42) or FBOP hypertension criterion (8%, n=4) would have been less. Based on this observation, the clinical panel determined that the NCCHC guideline had the greatest potential for identifying inmates who might benefit from screening. Panel members also commented that the clarity by which the NCCHC guideline defined and targeted risk factors would best help standardize T2D screening if future study findings support statewide implementation.

The panel members found that implementation of any of the three guidelines would help target screening. Although the pilot project was limited to one facility, given the findings that approximately 41% of 123 health records reviewed yielded a sample of 50 subjects (40.6%), and

46% (n=21) of these subjects had been diagnosed within 12 months of incarceration, the panel remarked that the incidence of T2D diagnosed during incarceration could potentially be significant. Given this, the panel supported standardized targeted T2D screening. Based on its review of risk factor data, the panel decided that the recommendations of the NCCHC guideline best addressed T2D risk in the sample. Implementation of this guideline as a prospective quality improvement study in a broader sample was proposed prior to considering statewide application.

Inmates with T2D who would have been screened based on guideline criteria.

Screening Guideline	Criteria for T2D Screening	Frequency	Percent
ADA	BMI \geq 25 with one additional risk factor Age \geq 45 High Risk Ethnicity Cardiovascular Disease Hypertension (Medication Therapy or Most Recent SBP \geq 140 or DBP \geq 90) Dyslipidemia (Fasting HDL \leq 35 or Fasting Serum Triglycerides \geq 250) Impaired Fasting Glucose (HgbA1c: 5.7 - 6.4 or Fasting Blood Glucose: 110 – 125)	42	84.00
NCCHC	Any of the below risk factors: Age > 45 BMI > 25 Hypertension Medication Therapy or Most Recent SBP \geq 140 or DBP \geq 90) Dyslipidemia(Fasting HDL \leq 35 or Fasting Serum Triglycerides \geq 250)	49	98.00
FBOP	Treated or Untreated (\geq 3 consecutive measurements) SBP 135 or DBP \geq 80) Otherwise, those with dyslipidemia or other disease states as clinically appropriate Cardiovascular Disease Dyslipidemia (Fasting HDL \leq 35 or Fasting Serum Triglycerides \geq 250)	4 10	8.00 20.00

Summary

The purpose of this quality improvement pilot project was to facilitate standardized T2D screening of inmates within a correctional system. Following a retrospective review of health records belonging to a sample of inmates diagnosed with T2D during incarceration at one of correctional system's facilities, the number and frequency of major risk factors were described. A clinical panel reviewed the project's findings, compared three diabetes management guidelines, and decided that the screening recommendations within the NCCHC diabetes management guideline best addressed T2D risk within the sample. Implementation of the NCCHC guideline as a prospective quality improvement study in a broader sample was proposed prior to considering statewide application.

This quality improvement pilot project was undertaken to improve T2D screening within a state correctional system by selecting one guideline to standardize screening. The number and frequency of selected T2D risk factors within a sample obtained from one correctional facility were described. The data derived from this sample was reviewed by a clinical panel which proposed the guideline that best addressed T2D risk in that sample. Implementation as a prospective quality improvement study in one or more correctional facilities was advised prior to considering statewide application. The information from this project can also be used to plan inmate education programs aimed to address reversible T2D risk factors.

The sample consisted of 50 adult male inmates who had been diagnosed with T2D during incarceration. A retrospective health record review was done using a data collection instrument created to document demographic and selected major T2D risk factor derived from recommendations of the CPGs being considered for implementation and which were retrievable from the inmate health record. As it was not known how many of the correctional system's diabetic inmates had been diagnosed with T2D during incarceration, facilities were ranked by the estimated number of those diagnosed with T2D. The intent was to start data collection at the highest-ranking facility and continue until the established sample size was obtained. The sample size was unexpectedly attained at the first facility in which data collection was undertaken.

Sample size and design limited generalizability to the correctional facility where the sample was obtained, and the clinical panel that reviewed the project's findings decided which screening recommendations best addressed T2D risk in the sample. Implementation as a prospective quality improvement study in a broader sample was recommended prior to statewide application. The panel considered the screening recommendations of three diabetes management guidelines: the 2011 American Diabetes Association's (ADA) Diabetes Management in

Correctional Institutions, the 2010 Federal Bureau of Prisons (FBOP) Diabetes Practice Guidelines, and the 2009 National Commission on Correctional Health Care (NCCHC) Diabetes Management Guidelines. Based on the finding that application of NCCHC guideline recommendations to major risk factors identified in the sample would yield screening in 98% (n=49) of the sample, which exceeded both the ADA (84%, n=42) and FBOP recommendations (8%, n=4 based on hypertension criteria; 20%, n=14 based on cardiovascular or dyslipidemia criteria) recommendations, the panel selected the NCCHC guideline for future implementation. The findings of this pilot project were also shared with the state department of correction administration for anticipated program planning aimed to address reversible T2D risk factors.

Discussion of Findings

A sample size of 50 subjects was selected for this quality improvement pilot project as it was believed that this would be sufficient for the purpose of the project. It was not known as to how many inmates with T2D had been diagnosed during incarceration. Anticipating that sampling of up to 450 health records might be needed to attain the sample size, it was projected that sampling would be done at several or more of the state correctional facilities which would have been representative of the state system. Obtaining the entire sample at the facility ranked highest for the estimated number of diabetic inmates was an unexpected finding. Also unexpected was the finding that the sample was obtained from a review of 123 records of inmates who potentially met inclusion criteria. Data belonging to one inmate who did not meet inclusion criteria (BMI could not be calculated using the selected instrument), and two inmate records that were discarded as sample size had been attained, were not entered into the database. For statistical and data cleansing tracking purposes, it would have been appropriate to have entered these data into the SPSS database.

Twenty-three (46%) of the subjects in the sample were diagnosed with T2D within 12 months of incarceration and 10% at or following 134 months of incarceration. Over half (54%) of those in the sample were 45 years of age or more at the time T2D was diagnosed. In comparison, approximately 20% of the correctional system's total adult male inmate population and 31% of inmates incarcerated at the facility where the sample was obtained were 45 years of age or more. The observation that the percentage of inmates at the facility where the sample was obtained estimated to be over age 45 exceeded that of the correctional system's total adult male population may be reflective of the correctional system's practice of cohorting inmates based on medical needs inclusive of age-related disabilities.

The review of the literature did not find studies that reported the relationship between BMI and T2D in the correctional population, and BMI data were unavailable for the total populations of the sample facility and state correctional system where the project was done. Therefore, the significance of finding 86% of subjects with a BMI of 25 or higher prior to T2D diagnosis is unknown. According to data reported by the Bureau of Justice Statistics (BJS) approximately 56% of all national prisoners would meet criteria for the high T2D racial/ethnic group (West, et al., 2010). In comparison, approximately 73% (n=15,956) of the state correctional system's total adult male population, 64% (n=1527) of the sample facility's adult male population, and 76% (n=38) of those in the sample met high T2D racial/ethnic group criteria.

A noticeable percentage (44%, n=22) of those in the sample were found to have multiple T2D demographic risk factors, specifically BMI over 25 and age 45 or more. As BMI tends to increase with age, and both are major T2D risk factors, this finding was not surprising. Thirty percent (n=7) of those with a BMI over 25 and age 45 or more also belonged to a high-risk

racial/ethnic group. As the majority of the sample facility population belonged to a high T2D racial/ethnic risk group, this finding was also not surprising.

The percentages of those in the sample found to have a history of impaired fasting glucose (prediabetes), hypertension, and cardiovascular disease exceeded respective projection estimates reported in the literature. The overall percentage of those (26%, n=13) with preexisting impaired fasting glucose (prediabetes) was over four times that of the prevalence projection (4.8%) for the total prison inmate population reported by Hornung et al. (2002). Compared with the 38% (n=19) of subjects in the sample found to have preexisting hypertension, overall prevalence estimates by Wilper et al. (2009) and Binswanger et al. (2009) were 31% and 30% respectively. Against the 8% (n=4) of those in the sample who were identified to have current or previous history of coronary vascular disease, pooled data derived from the projection estimates reported by Binswanger et al. (2009) approximates projected prevalence for cardiovascular disease at 3%. No projection estimates were found in the literature reviewed specific to dyslipidemia in the inmate population.

Although comparisons between the frequencies of T2D risk factors described in this quality improvement pilot project and disease conditions reported in projection estimates are reported, due to variations in sample size, data collection methods, and statistical analysis, the relevance of these findings is limited. Prevalence estimates reported in the literature in the correctional setting were heavily based on existing self-reporting survey data and it is possible that disease conditions were underreported. Other reasons for variations between the measured risk factor frequencies found in this of this pilot project and reported prediction estimates might include variations in age demographics and comorbidities.

Limitations

Due to limitations, the results of this quality improvement pilot project are generalizable only to adult male inmates diagnosed with T2D during incarceration and confined to the one correctional facility where the project was conducted. These limitations included limiting the sample to adult male inmates, obtaining the sample from one facility, and the inability to report the frequency of additional major T2D risk factor data (i.e. physical inactivity, first-degree relative with diabetes, acanthosis nigricans) data due to inadequacies in obtaining, documenting, or integrating information in the current inmate health record.

Although not collecting data belonging to female and adolescent males was believed appropriate based on small sample estimates of T2D in these populations, limiting the sample to adult males caused sampling bias. Unintentional sampling bias subsequently occurred through the process whereby subjects were selected. Even though facilities had been ranked according to the probability of subjects meeting the inclusion criteria, it had not been anticipated that the entire sample would be obtained from the population of a single facility.

A sample size of 50 subjects had been deemed adequate for this pilot project as it was not known how many inmates within the correctional system had been diagnosed with T2D during incarceration and a descriptive design was planned to report quantitative data. Surprisingly, this sample was obtained from the review of 123 health records belonging to inmates housed at the first facility where data were collected. Based on statistical analysis, 40.2% of the inmates whose records were reviewed had been diagnosed with T2D during incarceration. Although further analysis suggested that the standard error for the estimated prevalence rate would have been relatively precise regardless of the number of records reviewed at the facility where the sample was obtained, this estimate may not be representative of all inmates diagnosed with T2D during incarceration within the state correctional system. It is possible that the system's practice to consider inmate medical needs when determining housing placements resulted in a

disproportionate number of inmates with or at high risk for developing T2D during incarceration being housed at the facility sampled. If these subjects had substantial comorbidities, the prevalence of major T2D diabetes risk factors of inmates included in this sample could have been greater than those of potential subjects housing inmates with less complex medical needs.

Because information not routinely obtained by health services staff or documented in the inmate health record could not be collected, frequencies of other major T2D risk factors named in diabetes guideline screening recommendations (i.e. physical inactivity, first-degree relative with diabetes, acanthosis nigricans) were not obtained. Also, as the sample excluded female inmates, the frequency of additional major T2D risk factors specific to females (i.e. history of gestational diabetes, polycystic ovarian disease, or having delivered a baby weighing > 9 pounds) was not reported. Descriptions of less-powerful and less prevalent T2D risk factors (i.e. history of atypical antipsychotic medication therapy, psychosis, human immunodeficiency viral infection, low socioeconomic level, less than high school education, and health illiteracy) were not considered because they were not named major T2D screening risk factors in the recommendations of the screening guidelines reviewed.

Several factors encompassing the documentation of major T2D risk factors might have resulted in underreporting frequency for these conditions. These factors include the integrity of the existing paper inmate health record and lack of consistent T2D screening prior to or during incarceration.

As data collection was limited to that found in the health record, and as the correctional system utilized a paper inmate health record, T2D risk factor information could have been documented incorrectly or incompletely, misread, or missing. Reasons for this include misfiling and illegible handwriting. As a mechanism did not exist to identify inmates who would have

meet inclusion criteria but were being treated with dietary restrictions alone, these inmates were not included in the sample. The risk for underreporting could have been decreased if an electronic health record (EHR) had been in use for documentation and tracking purposes.

Implications and Recommendations

As with the community population, the incidence of T2D in inmates is expected to increase. Socioeconomic costs associated with T2D and its complications are significant. Although screening may prevent or delay the onset of T2D, universal screening has been shown not to be cost effective and is not recommended (Chatterjee et al., 2013; Hoerger et al., 2004). By describing selected T2D major risk factors identified in a sample of those diagnosed during incarceration, a clinical panel recommended the 2009 NCCHC Diabetes Management Guideline for implementation as a prospective quality improvement study. Increasing sample size, sampling across multiple facilities, including subjects belonging to female and adult youth groups, randomly selecting subjects that meet inclusion criteria statewide, and obtaining data for those major risk factors that had not been reported would help report major T2D risk factor data that s are more representative of the entire correctional system. In addition, as the prevalence of less-powerful T2D risk factors may be greater in the correctional population than in the community, reporting the frequency of these risk factors may justify additional conditions for which targeting might be studied.

Implementation of an electronic health record (EHR) would help ensure more complete, accurate, and timely documentation of inmate health histories and assessments and support data retrieval. A direct link to the pharmacy database would be useful to retrieve the most current medication prescription information. Links to custody information concerning inmate level of education, socioeconomic status prior to incarceration, work and recreation history, and

commissary usage would allow ready access to information relative to health promotion.

Additionally, an EHR would facilitate the review and collection of data pertaining to large samples across and between correctional facilities.

In addition to implementing measures to control limitations identified in the completed project, an important concern that should be addressed in the design of future T2D quality improvement initiatives is the potential number of inmates who might be at risk for T2D but are just below the selected guideline's BMI and age screening parameters. A possible solution might be to shorten the screening interval time for those inmates meeting one or more of these criterion.

Summary

The aim of this quality improvement pilot project was to facilitate standardized T2D screening of inmates within a correctional system, specifically, to describe the number and frequency of selected major T2D risk factors in a sample of inmates diagnosed with T2D during incarceration for review by a clinical panel tasked with identifying the guideline screening recommendations that best addressed T2D risk in the sample. A data collection instrument was developed to document risk factor and related information and to facilitate the sample selection process. Following its review of prevalence data of preexisting major T2D risk factors in a sample of inmates diagnosed with T2D during incarceration, a clinical panel recommended the 2009 NCCHC screening guideline for future implementation as a prospective quality improvement study.

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Data Collection Instrument

Date of Health record Review (m/d/yr): ____/____/____

Subject ID (Simple ordinal number [1,2,3...]in numerical order) : _____

Age (in years): _____

Month/Year of Incarceration: ____/____/____

Height (in inches): _____ Weight (in pounds): _____ Calculated BMI : _____

Race (check one): Caucasian (White) ☐ African/American (Black) ☐ Hispanic/Latino ☐
 Native American ☐ Asian ☐ Other ☐ _____

Section Criteria	No (If No, Stop Here)	Yes (if Yes proceed to next question)
Diagnosed with diabetes?		
Diagnosed during incarceration?		
Diagnosed with T2D?		
Month/Year of T2D Diagnosis (relevant only if diagnosed during incarceration):	/	
Number of CDOC facilities the subject received medical services from prior to T2D diagnosis (limited to the admission in which the diagnosis was made):		
Major T2D Risk Factors Prior to T2D Diagnosis?	No	Yes
Age ≥ 45 ?		
BMI ≥ 25 ?		
On lipid lowering medication or documented fasting high density lipoprotein level of 35 or less?		
On lipid lowering medication or documented fasting serum triglyceride level ≥ 250 mg?		
Documented history of impaired fasting glucose/prediabetes (HgbA1c 5.7 to 6.4)?		
Documented history of impaired fasting glucose/prediabetes (fasting glucose 110 to 125 mg/dl)?		
Belonging to a high risk racial/ethnic group (Black, Hispanic/Latino, Native North American, or Asian)?		
Documented current or past history of coronary vascular disease?		
On antihypertensive therapy or most recent documented SBP ≥ 140 or DBP ≥ 90 ?		
Sustained (3 or more consecutive treated or untreated BP measurements) SBP > 135 or DBP > 80		

Comments:

Body Mass Index (BMI)

		WEIGHT (lb)																															
	120	130	140	150	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330	340	350									
4' 5"	30	33	35	38	40	43	45	48	50	53	55	58	60	63	65	68	70	73	75	78	80	83	85	88									
4' 6"	29	31	34	36	39	41	43	46	48	51	53	55	58	60	63	65	68	70	72	75	77	80	82	84									
4' 7"	28	30	33	35	37	40	42	44	46	49	51	53	56	58	60	63	65	67	70	72	74	77	79	81									
4' 8"	27	29	31	34	36	38	40	43	45	47	49	52	54	56	58	61	63	65	67	69	72	74	76	78									
4' 9"	26	28	30	32	35	37	39	41	43	45	48	50	52	54	56	58	61	63	65	67	69	71	74	76									
4' 10"	25	27	29	31	33	36	38	40	42	44	46	48	50	52	54	56	59	61	63	65	67	69	71	73									
4' 11"	24	26	28	30	32	34	36	38	40	42	44	46	48	50	53	55	57	59	61	63	65	67	69	71									
5' 0"	23	25	27	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	62	64	66	68									
5' 1"	23	25	26	28	30	32	34	36	38	40	42	43	45	47	49	51	53	55	57	59	60	62	64	66									
5' 2"	22	24	26	27	29	31	33	35	37	38	40	42	44	46	48	49	51	53	55	57	59	60	62	64									
5' 3"	21	23	25	27	28	30	32	34	35	37	39	41	43	44	46	48	50	51	53	55	57	58	60	62									
5' 4"	21	22	24	26	27	29	31	33	34	36	38	39	41	43	45	46	48	50	51	53	55	57	58	60									
5' 5"	20	22	23	25	27	28	30	32	33	35	37	38	40	42	43	45	47	48	50	52	53	55	57	58									
5' 6"	19	21	23	24	26	27	29	31	32	34	36	37	39	40	42	44	45	47	48	50	52	53	55	56									
5' 7"	19	20	22	23	25	27	28	30	31	33	34	36	38	39	41	42	44	45	47	49	50	52	53	55									
5' 8"	18	20	21	23	24	26	27	29	30	32	33	35	36	38	40	41	43	44	46	47	49	50	52	53									
5' 9"	18	19	21	22	24	25	27	28	30	31	32	34	35	37	38	40	41	43	44	46	47	49	50	52									
5' 10"	17	19	20	22	23	24	26	27	29	30	32	33	34	36	37	39	40	42	43	44	46	47	49	50									
5' 11"	17	18	20	21	22	24	25	26	28	29	31	32	33	35	36	38	39	40	42	43	45	46	47	49									
6' 0"	16	18	19	20	22	23	24	26	27	28	30	31	33	34	35	37	38	39	41	42	43	45	46	47									
6' 1"	16	17	18	20	21	22	24	25	26	28	29	30	32	33	34	36	37	38	40	41	42	44	45	46									
6' 2"	15	17	18	19	21	22	23	24	26	27	28	30	31	32	33	35	36	37	39	40	41	42	44	45									
6' 3"	15	16	17	19	20	21	22	24	25	26	27	29	30	31	32	34	35	36	37	39	40	41	42	44									
6' 4"	15	16	17	18	19	21	22	23	24	26	27	28	29	30	32	33	34	35	37	38	39	40	41	43									
6' 5"	14	15	17	18	19	20	21	23	24	25	26	27	28	30	31	32	33	34	36	37	38	39	40	42									
6' 6"	14	15	16	17	18	20	21	22	23	24	25	27	28	29	30	31	32	34	35	36	37	38	39	40									
6' 7"	14	15	16	17	18	19	20	21	23	24	25	26	27	28	29	30	32	33	34	35	36	37	38	39									
6' 8"	13	14	15	16	18	19	20	21	22	23	24	25	26	27	29	30	31	32	33	34	35	36	37	38									
6' 9"	13	14	15	16	17	18	19	20	21	23	24	25	26	27	28	29	30	31	32	33	34	35	36	38									
6' 10"	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	35	36	37									
							Less risk																									More risk	

☐ Underweight

☒ Low Risk

☒ Overweight

☒ High Risk with the medical diagnosis of obesity

www.dr-richardson.com/bmi-assessment.html



STATE OF CONNECTICUT
DEPARTMENT OF CORRECTION
24 WOLCOTT HILL ROAD
WETHERSFIELD, CONNECTICUT 06109

July 19, 2011

Mary Ellen Castro, MSN, APRN
Assistant Director of Nursing & Patient Care Services
University of Connecticut Health Center/Correctional Managed Health Care
263 Farmington Avenue
Farmington, CT 06030-5389

Dear Ms. Castro:

I am writing to inform you that your research project "Diabetes Screening in Inmates: A Quality Improvement Pilot Project" has been approved by the CT Department of Correction. Please submit your IRB approval to Michelle Altomare, at Michelle.Altomare@po.state.ct.us once it has been approved.

If you have any further questions please feel free to contact me (860) 692-7817.

Sincerely,

A handwritten signature in black ink that reads "Patrick Hynes".

Patrick Hynes, Ph.D.
Director, Best Practices Unit

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University of Connecticut Health Center
Human Subjects Protection Office



To: Deborah Shelton
Principal Investigator
Occupational Medicine

From: UConn Health Center
IRB Office

Date: August 26, 2011

Re: Final Approval of Full Board Project

IRB Number: 12-027S-2

IRB Panel: Panel 02

Project Title: Diabetes Screening in Inmates: A Quality Improvement Pilot Project

Sponsor / Funding Agency: Principal Investigator~

Approved Investigators: Shelton, Deborah~Panosky, Denise~

Risk Level: Minimal

Protocol Version: Version Date June 18, 2011

Permissible Category(ies): 45CFR46.306(a)(2)(i)

The study referenced above was reviewed at the Institutional Review Board meeting convened on 8/15/2011 and has been given final approval as of 08/15/2011 and is valid through 8/10/2012.

Federal regulations and guidance require that continuing review occur within 365 days of the convened meeting date. Therefore, your study is approved as valid through. Should you wish to continue this study beyond that date, you must apply to the Institutional Review Board Office for approval to do so. You will receive one reminder notice to request continuation approximately eight weeks prior to the expiration of the approval of the study. The Board determined this study to be of minimal risk. Therefore, if the study does not involve the use of investigational drugs or devices, does not enroll prisoners, and no additional risks are identified, you may request expedited continuation under category 9. All studies approved by the IRB are subject to audit by the Research Compliance Monitor.

It is the responsibility of the PI to ensure that all investigators and staff associated with this study 1) follow the approved protocol; 2) use the approved forms; 3) comply with all IRB policies including the reporting of non-compliance with the approved protocol, unanticipated problems involving risk to subjects or others, adverse events, and any suspensions or terminations of IRB approval; and 4) comply with applicable regulations and the requirements or determinations of the IRB. Policies are available from the web site, <http://hspo.uconn.edu/>. If applicable to your study, copies of the stamped and dated consent form must be used when obtaining consent and the form must be signed and dated by both the participant and individual obtaining consent. PI's are also responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research.

Approval from the IRB for any modification or addition to the protocol, forms or recruitment materials, must be obtained prior to implementation, except when necessary to eliminate immediate hazards to the subjects in which case the change must be reported within 5 days of occurrence. Administrative changes that pose no increased risk (e.g. correction of typographical errors, approval of an advertisement) may be approved through expedited review however the Chair reserves the right to send any request for modification to the full board.

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263 Farmington Avenue
Farmington, Connecticut 06030-3926

Telephone: (860) 679-3054
Facsimile: (860) 679-1005

Appendix E



University of Connecticut Health Center
Human Subjects Protection Office



To: Deborah Shelton
Principal Investigator
Occupational Medicine

From: UConn Health Center
IRB Office

Date: July 13, 2012

Re: Final Approval for Continuation of Project

Review Category: Expedited **Expedited Category:** 8C

IRB Number: 12-027S-2 **IRB Panel:** Panel 02

Project Title: Diabetes Screening in Inmates: A Quality Improvement Pilot Project

Sponsor / Funding Agency: Principal Investigator~

Investigators Involved with Long Term Follow-up or Analysis: Shelton, Deborah~Panosky, Denise~

Risk Level: Minimal

Permissible Category(ies): 45CFR46.306(a)(2)(i)

The study referenced above was approved for continuation on 7/10/2012 and remains valid through 7/9/2013. Should you wish to continue this study beyond that date you must apply to the Institutional Review Board Office for continuation of the study. All approved studies are subject to audit by the Research Compliance Monitor.

It is the responsibility of the PI to ensure that all investigators and staff associated with this study 1) follow the approved protocol; 2) use the approved forms; 3) comply with all IRB policies including the reporting of non-compliance with the approved protocol, unanticipated problems involving risk to subjects or others, adverse events, and any suspensions or terminations of IRB approval; and 4) comply with applicable regulations and the requirements or determinations of the IRB. Policies are available from the web site, <http://hspo.uchc.edu/>.

If applicable to your study, copies of the stamped and dated consent form must be used when obtaining consent and the form must be signed and dated by both the participant and individual obtaining consent. PI's are also responsible for ensuring that IRB approval has been obtained and maintained at any collaborating sites involved in the research.

Approval from the IRB for any modification or addition to the protocol, forms or recruitment materials, must be obtained prior to implementation, except when necessary to eliminate immediate hazards to the subjects in which case the change must be reported within 5 days of occurrence. Administrative changes that pose no increased risk (e.g. correction of typographical errors, approval of an advertisement) may be approved through expedited review however the Chair reserves the right to send any request for modification to the full board.

c: Mary Ellen Castro

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Telephone: (860) 679-3054

Facsimile: (860) 679-1005

UConn Health Center, 263 Farmington Avenue, Farmington, CT 06030-3926